

Welcome!

Please be seated by 8:55 AM ET

The webinar will go live at 9:00 AM ET



Advisory Panel on Addressing Disparities: In-Person Meeting

October 24th, 2016

9:00 AM – 4:45 PM ET



Welcome, Introductions, and Setting the Stage

Romana Hasnain-Wynia, PhD, MS

Program Director, *Addressing Disparities*

Cheryl Pegus, MD, MPH,

Chair, Addressing Disparities Advisory Panel

Elizabeth A. Jacobs, MD, MAPP, FACP

Co-Chair, Addressing Disparities Advisory Panel



Housekeeping

- Today's meeting is open to the public and is being recorded
 - Members of the public are invited to listen to the teleconference and view the webinar
 - Meeting materials can be found on the PCORI website
 - Anyone may submit a comment through the webinar chat function, although no public comment period is scheduled
- Visit www.pcori.org/events for more information



Housekeeping (cont.)

- We ask that panelists stand up their tent cards when they would like to speak and use the microphones
- Please remember to state your name when you speak



Agenda Item	Time
Welcome, Introductions, and Setting the Stage	9:00 AM
What Direction is PCORI Moving	9:20 AM
Addressing Disparities Program Updates	9:50 AM
Awardee Presentation: Nueva Vida Intervention: Improving QOL in Latina Breast Cancer Survivors and Their Caregivers	10:45 AM
Overview of Conflict of Interest Forms	11:45 AM
Addressing Disparities Advisory Panel Photo	12:00 PM
Lunch	12:15 PM
Addressing Disparities Program Updates: Targeted Portfolio and Programmatic Clinical Studies Portfolio	1:00 PM
Topic Brief Discussion: Sleep Apnea	1:45 PM
Topic Brief Discussion: Eye Drops vs. Laser Surgery	
Topics Under Consideration: Readmissions and Autism	2:30 PM
Vision of Science at PCORI and Evidence Synthesis to Inform Comparative Effectiveness Research	3:00 PM
Activities at PCORI	4:00 PM
Wrap Up and Next Steps	4:30 PM
Adjourn	4:45 PM

Introductions

- Please quickly state the following:
 - Name
 - Stakeholder group you represent
 - Position title and organization
 - Icebreaker response



Introductions: Current Panelists



Introductions (cont.)

Cheryl Pegus, MD, MPH (*Chair*)

Director of the Division of General Internal Medicine and Clinical
Innovation, *NYU Langone Medical Center*

Representing: Patients, Caregivers, and Patient Advocates



Introductions (cont.)

Elizabeth A. Jacobs, MD, MAPP, FACP (Co-Chair)

Associate Vice Chair, Health Services Research in the Department of Medicine and Population Health Science, *University of Wisconsin*

Representing: Researchers



Introductions (cont.)

Alfiee M. Breland-Noble, PhD, MHSc

Director, The AAKOMA Project, *Georgetown University Medical Center*,
Associate Professor, Psychiatry, *Georgetown University Medical Center*

Representing: Researchers



Introductions (cont.)

Ronald Copeland, MD, FACS

Senior Vice President of National Diversity and Inclusion Strategy and Policy and Chief Diversity and Inclusion Officer, *Kaiser Permanente*

Representing: Health Systems



Introductions (cont.)

Martina Gallagher, PhD, MSN, BSN

Assistant Professor, *University of Texas Health Science Center*

Representing: Clinicians



Introductions (cont.)

Sinsi Hernández-Cancio, JD

Director of Health Equity, *Families USA*

Representing: Patients, Caregivers, and Patient Advocates



Introductions (cont.)

Grant Jones

Founder, Executive Director, *Center for African American Health*

Representing: Patients, Caregivers, and Patient Advocates



Introductions (cont.)

Patrick Kitzman, PhD, MS

Associate Professor, Physical Therapy, *University of Kentucky*

Representing: Clinicians



Introductions (cont.)

Barbara L. Kornblau, JD, OTR/L

CEO, Coalition for Disability Health Equity

Representing: Patients, Caregivers, and Patient Advocates



Introductions (cont.)

Kenneth Mayer, MD

Medical Research Director, Co-Chair, *The Fenway Institute*;
Professor, *Harvard Medical School and School of Public Health*

Representing: Researchers



Introductions (cont.)

Doriane C. Miller, MD

Director, *Center for Community Health and Vitality* University of
Chicago Medical Center

Representing: Patients, Caregivers, and Patient Advocates



Introductions (cont.)

Alan R. Morse, JD, PhD

President and Chief Executive Officer, *Lighthouse Guild International*;
Adjunct Professor of Ophthalmology, *Columbia University*

Representing: Health Systems



Introductions (cont.)

Danielle Pere, MPM

Associate Executive Director, *American College of Preventive Medicine*

Representing: Clinicians



Introductions (cont.)

Elinor Schoenfeld, PhD

Research Associate Professor of Preventive Medicine and
Ophthalmology, *Stony Brook University*

Representing: Researchers



Introductions: New Panelists



Introductions (cont.)

Terrie Black DNP, MBA, BSN, RN, CRRN, FAHA

Clinical Assistant Professor, *University of Massachusetts, Amherst*;
Nurse Surveyor, *The Joint Commission*

Representing: Clinicians



Introductions (cont.)

Deidra C. Crews, MD, ScM, FASN, FACP

Associate Professor of Medicine in the Division of Nephrology, *Johns Hopkins University*;

Associate Vice Chair for Diversity and Inclusion of the Department of Medicine, *Johns Hopkins University School of Medicine*

Representing: Clinicians



Introductions (cont.)

Christine Joseph, PhD, MPH

Senior Epidemiologist, *Henry Ford Health System*;
Director, *Henry Ford Health System Health Disparities Research Collaborative*

Representing: Researchers



Introductions (cont.)

Donald Klepser, PhD, MBA

Associate Professor, *University of Nebraska Medical Center*

Representing: Researchers



Introductions (cont.)

Ana Maria Lopez, MD, MPH, FACP

Associate Vice President for Health Equity and Inclusion, *University of Utah Health Sciences*;

Director of the Collaboration and Engagement Team (CTSA); *University of Utah*

Representing: Clinicians



Introductions (cont.)

Umbereen S. Nehal, MD, MPH

Assistant Professor, *University of Massachusetts Medical School*;
Physician, *Boston Medical Center*

Representing: Payers



Introductions (cont.)

Tung Nguyen, MD

Special Government Employee, *Department of Education*;
Endowed Chair in General Internal Medicine, Professor of Medicine,
University of California San Francisco (UCSF)

Representing: Researchers



Addressing Disparities Program Staff



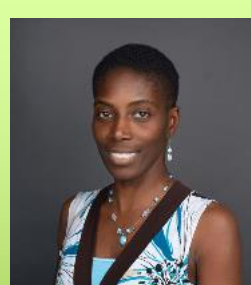
**Romana
Hasnain-Wynia,
PhD, MS**
Program Director



**Ayodola
Anise, MHS**
Program
Officer



**Kaitlynn
Robinson-
Ector, MPH**
Program
Associate



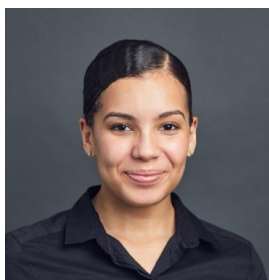
**Tomica
Singleton**
Sr. Administrative
Assistant



**Parag
Aggarwal, PhD**
Senior Program
Officer



**Julia
Anderson,
MEM, MPH**
Program
Associate



**Dionna
Atkinson**
Program
Assistant



**Alyzza Dill,
MPH**
Program
Associate



**Cathy
Gurgol, MS**
Program
Officer



**Mira Grieser,
MHS**
Program
Officer



**Soknornta
Prum, MPH**
Program
Associate



**Marisa Torres,
MPH**
Program Associate



What Direction is PCORI Moving

Romana Hasnain-Wynia, PhD, MS

Program Director, *Addressing Disparities*



PCORI Research Funding Opportunities

1

Broad Funding Announcements

2

Targeted Funding Announcements

3

Pragmatic Clinical Studies Funding Announcements



PCORI's Current Focus: Investments and Activities

PCORI's focus is moving towards:

- Increasing investment for head-to-head CER studies
 - Including discussion on how best to address disparities populations
- Funding more pragmatic clinical CER studies
- Focusing more on funding research that complements or fills gaps in our current portfolio and less on prioritization
- Identifying evidence gaps and CER questions from evidence syntheses, systematic reviews, and practice guidelines
- Evaluating the impact of the portfolio and of clusters of funded research with results
- Continuing to build upon collaborations with external organizations (e.g., NIH, CDC, AHRQ)



PCORI's Current Focus: Outcomes

- Overall **PCORI seeks studies** that **include**:
 - Patient-centered outcomes
 - Patient reported outcomes
 - Clinical outcomes
- Major interest in **short-term** or **intermediate outcomes** that can be measured within **3 – 5 years**



Merit Review Criteria

Criterion 1. Potential for the study to fill critical gaps in evidence

Criterion 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care

Criterion 3. Scientific merit (research design, analysis, and outcomes)

(NEW) Criterion 4. Investigator(s) and environment

Criterion 5. Patient-centeredness

Criterion 6. Patient and stakeholder engagement



Distinguishing Patient Centeredness and Patient and Stakeholder Engagement

Criterion 5. Patient-centeredness

- Patient-centered outcomes research (PCOR) is focused on questions and outcomes that matter to patients and their caregivers
 - Describing which outcomes (including benefits and harms) are important to patients and are included in the study
 - Identifying interventions that are the best options for comparison

Criterion 6. Patient and stakeholder engagement

- Engaging patients, caregivers, and other stakeholders in all aspect of the research
 - Defining topics and formulating research questions
 - Identifying a study population
 - Choosing interventions, comparators, and outcomes
 - Conducting the study and analyzing results
 - Disseminating findings



Funding Through 2019

- What does this means for **3 - 5 year projects** that are **funded** in **2017**?
 - **3 year** studies will be **funded** through **2020**
 - **5 year** studies will be **funded** through **2022**



Discussion

Addressing Disparities Program Updates

Romana Hasnain-Wynia, PhD, MS

Program Director, Addressing Disparities

Cathy Gurgol, MS

Program Officer, Addressing Disparities



Addressing Disparities Program: Mission Statement

PCORI's Vision, Mission, Strategic Plan

Program's Mission Statement

To **reduce disparities** in healthcare outcomes and **advance equity** in health and healthcare

Program's Guiding Principle

To support comparative effectiveness research that will identify best options for reducing and **eliminating disparities**



Addressing Disparities Program: Goals

Identify Research Questions

- **Identify** high-priority **research questions** relevant to reducing and eliminating disparities in health and healthcare outcomes

Fund Research

- **Fund** comparative effectiveness **research** with the highest potential to reduce and eliminate health and healthcare disparities

Disseminate Promising/ Best Practices

- **Disseminate** and facilitate the adoption of **promising/best practices** to reduce and eliminate health and healthcare disparities



Addressing Disparities Goal 1: Identify High Priority Research Questions

Priority Topics			
Health communication models	Major vascular events	Hypertension in minorities*	Interventions for improving perinatal outcomes**
Reduce lower-extremity amputations in minorities**	Integration of mental and behavioral health services into primary care settings**	Care coordination in primary care to address disparities and advance equity	Improving the continuum of care for individuals 0 to 26 years of age with disabilities
Effective communication for people with disabilities	Innovative outreach to enhance utilization of mental health services among underserved youth	Interventions to reduce initiation of use of tobacco and promote tobacco cessation among high-risk and vulnerable populations**	Improving the Continuum of Care for Patients with Disabilities
Quality of Care for LGBT Populations	Interventions to Reduce Disparities in the Efficacy of Treatments for Sleep Disorders	Unintentional overdose and substance dependence of pain relievers	Disease identification/risk assessment and therapeutic strategies for autism spectrum disorders

Addressing Disparities Goal 2: Fund Research

Funded **67 studies** for a total of **\$187 million** across **21 states** and Washington DC

- **Targeted Portfolio: 12 Studies** for a total of **\$64.8 million**
- **Pragmatic Clinical Studies Portfolio: 2 studies** for a total of **\$25.9 million**
- **Broad Portfolio: 53 studies** for a total cost of **\$96.3 million**



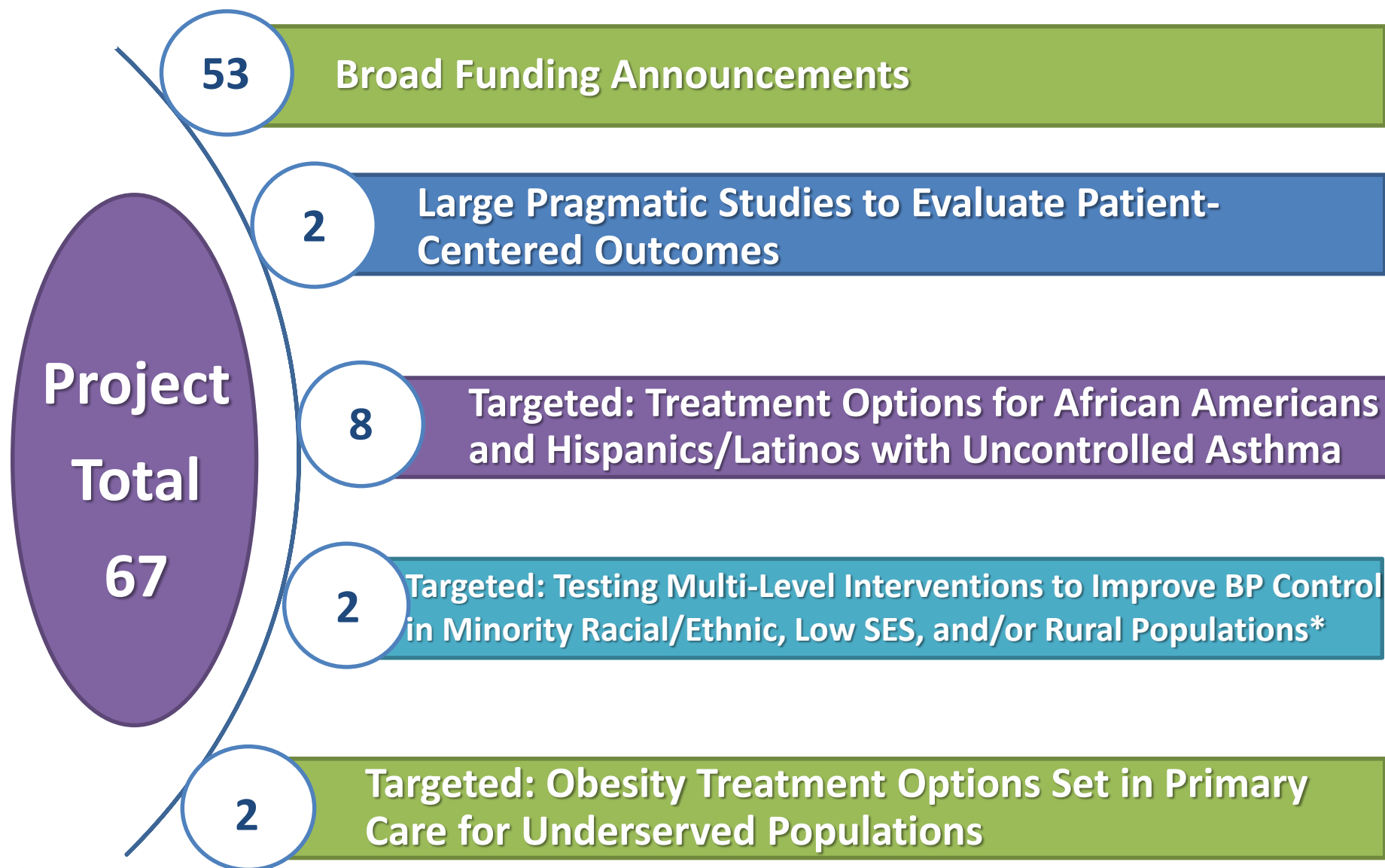
Addressing Disparities: Goal 3 - Disseminate Promising/Best Practices

Examples:

- Collaboration with the PCORI Dissemination and Implementation Program
 - Identify ways of sharing information
- Discuss PCORI's efforts on Capitol Hill with policy makers
- Engagement with an array of stakeholder groups
 - Identify opportunities to obtain feedback from stakeholders and end-user of study results
- Evidence to Action Network
 - Convene key stakeholders and end users
 - Build a collaborative
 - Facilitate engagement of end users



Addressing Disparities Portfolio



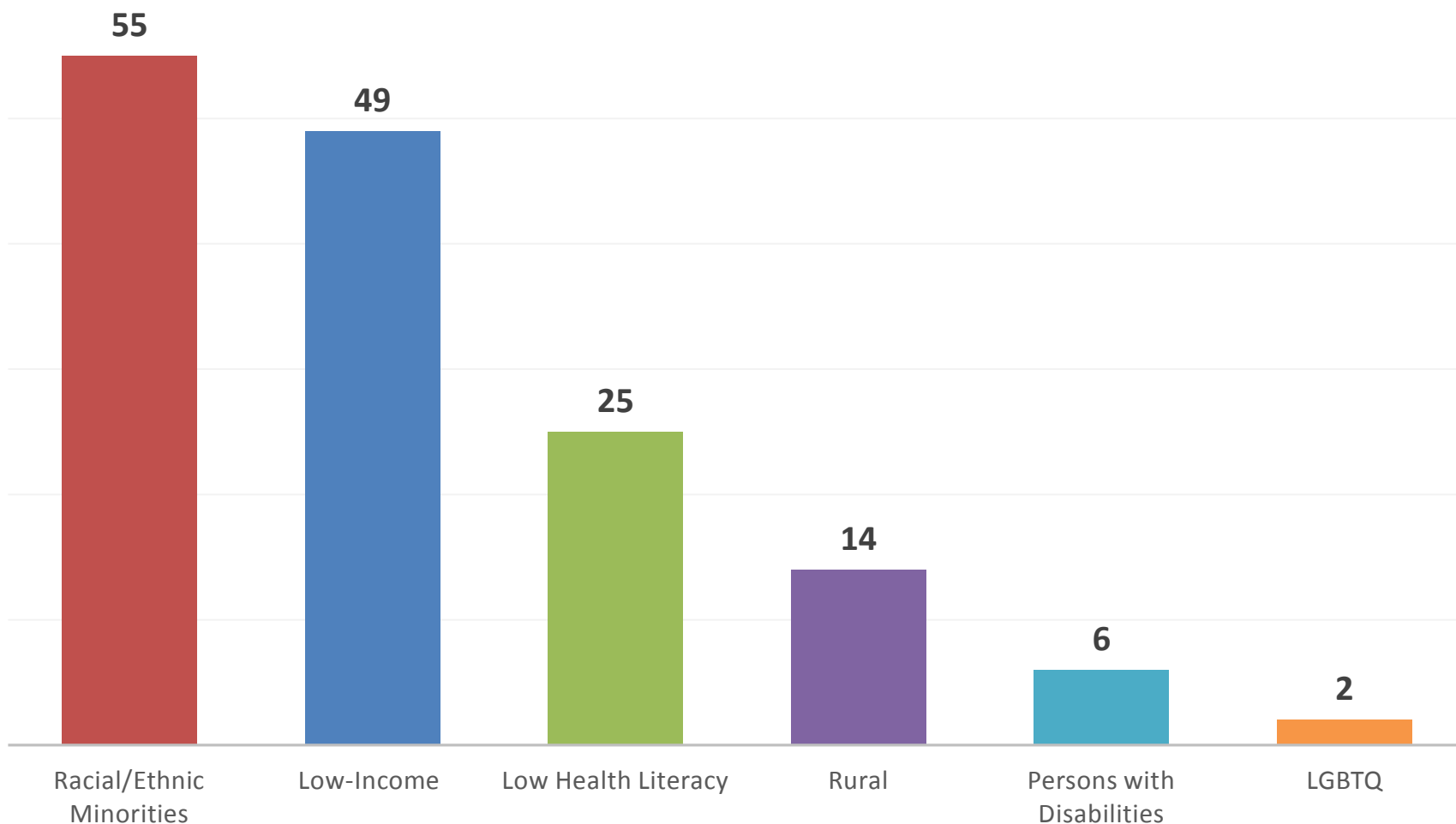
Addressing Disparities Portfolio: Health Conditions

Condition	Number
Mental/Behavioral Health	15
Respiratory Diseases	10
Cardiovascular Health	9
Nutritional and Metabolic Disorders	6
Neurological Disorders	5
Multiple/co-morbid chronic conditions	4
Cancer	3
Reproductive and Perinatal Health	2
Liver Disease	2
Functional Limitation and Disabilities	1
Other	10
Grand Total	67



Addressing Disparities Populations of Interest

*not mutually exclusive



Addressing Disparities Broad Portfolio Updates and Completed Projects

Cathy Gurgol, MS

Program Officer, Addressing Disparities



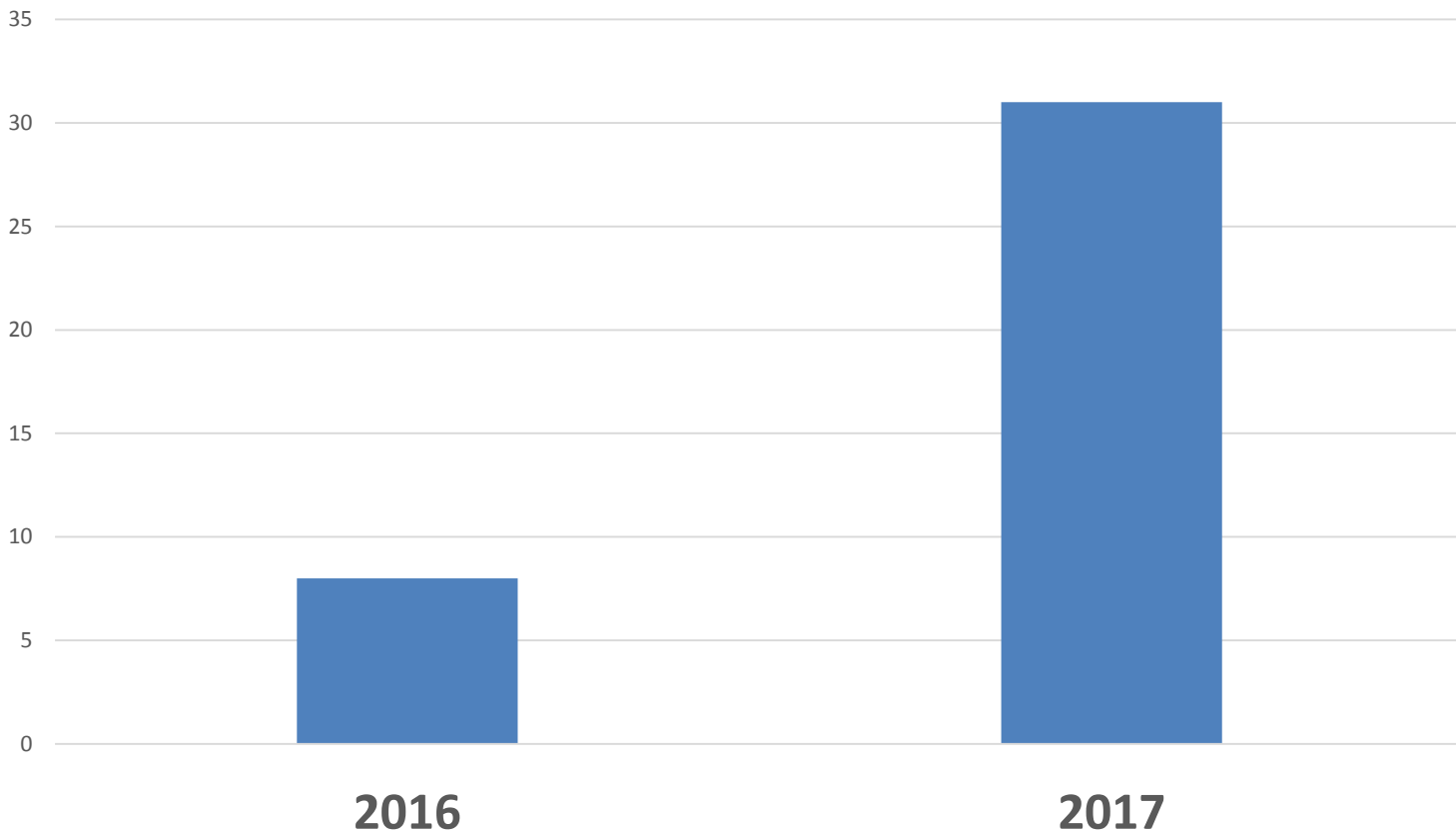
AD Broad Portfolio Updates

- **General parameters of the Broad PFA:**
 - Investigator-initiated research
 - 3 years duration
 - Budget: \$1.5 million (direct costs)
- **Current status:**
 - Funded 53 projects
 - Total budget: \$91 Million



AD Broad Portfolio Updates

Broad Projects Ending by Year



As of September 2016



Completed Projects

Decisional Dilemma: (Serious Mental Illness)

Individual with serious mental illness: I would like to manage my healthcare better. Should I participate in a program where my peers help me gain the knowledge I need or continue receiving standard treatment from the community mental health clinic? The peer program is time intensive but standard care may not meet my needs.



Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill (PI: John Brekke, PhD; University of Southern California)

- **Research Question:** To what degree can peer health navigation impact the health disparities of the SMI?
- **Comparison:** Peer navigator “Bridge” intervention compared to treatment as usual
- **Sample:** N=151 **Population:** Low-income, individuals with SMI, Latino
- **Outcomes:** use of ambulatory and outpatient care, use of ER and urgent care, health status, health care self-efficacy, satisfaction with care, HRQOL, functional outcomes, and self-esteem.
- **Findings:** Peer navigation group had better improvement in access and use of primary care services, better quality relationship between PCP and patient, increased confidence in self-management skills, and reductions in pain, compared to the usual treatment group.
- **Potential Impact:** Promising peer-delivered intervention to address the physical health and health care needs of individuals with serious mental illnesses.



Decisional Dilemma: Parkinson's Disease

Individual with Parkinson's Disease: It's difficult for me to travel to my doctor appointments but I'm not sure if seeing a doctor over video will actually work and make me feel as though I'm being cared for. But being able to get care while being home would be easier. Should I continue seeing my Parkinson's Disease specialist in person or should I seek care via videoconference?



Using technology to deliver multi-disciplinary care to individuals with Parkinson disease in their homes (PI: Ray Dorsey, MD; University of Rochester)

- **Research Question:** Does using video conferencing to provide patient care to patients with Parkinson disease directly in their homes feasible, improve QOL enhance quality of care, and provide additional values, like save time, reduce travel?
- **Comparison:** Telehealth Parkinson's care by a specialist compared to usual in-person Parkinson's care
- **Sample:** N=195 enrolled; **Population:** People with Parkinson's disease (PD)/limited access to care
- **Outcomes:** Parkinson Disease-specific QOL, feasibility, quality of care, depression
- **Findings:** No difference between groups in QOL. However, the study demonstrated feasibility of delivering specialty disease care to people with Parkinson's disease. Patients were overwhelmingly satisfied with the intervention.
- **Potential Impact:** Video conferencing for people with Parkinson's Disease is feasible and may be preferable to these patients. Through reduction of barriers and refinement of telehealth services, individuals with conditions like PD can receive care at home.



Next Steps

- Final Research Reports will undergo PCORI's Peer Review process
 - Final Research Reports will be posted on PCORI's website 12 months after acceptance by PCORI
 - Abstracts will be posted on PCORI's website 90 days after Final Research Report is accepted by PCORI
- Awardees may apply for Dissemination and Implementation funding
- Awardees will continue to work with their stakeholders to disseminate their findings



Awardee Presentation: Nueva Vida Intervention: Improving QOL in Latina Breast Cancer Survivors and their Caregivers

Kristi Graves, PhD, MA

Associate Professor, *Georgetown University*





PATIENT CARE
RESEARCH
EDUCATION
COMMUNITY

Nueva Vida Intervention to Improve Quality of Life in Latina Breast Cancer Survivors and their Caregivers

Kristi D. Graves, Ph.D.

October 24, 2016



A Comprehensive Cancer Center Designated
by the National Cancer Institute

<http://lombardi.georgetown.edu>
Lombardi CancerLine: 202.444.4000

Contract Supported by: AD-12-11-5365

Outline

1. Background
2. Involvement of Patients and Stakeholders throughout Nueva Vida Intervention
3. Results to Date
4. Implications, Implementation, Dissemination Ideas



Disparities: Quality of Life (QOL)

- Latina breast cancer survivors have worse QOL than non-Latina White survivors
 - Physical Functioning, Social Functioning, Anxiety, Depression, Pain and Fatigue
- Subgroups of Latinas (immigrants, monolingual Spanish) appear to have worse anxiety and depression
- Little data on the QOL of Latina survivors' caregivers



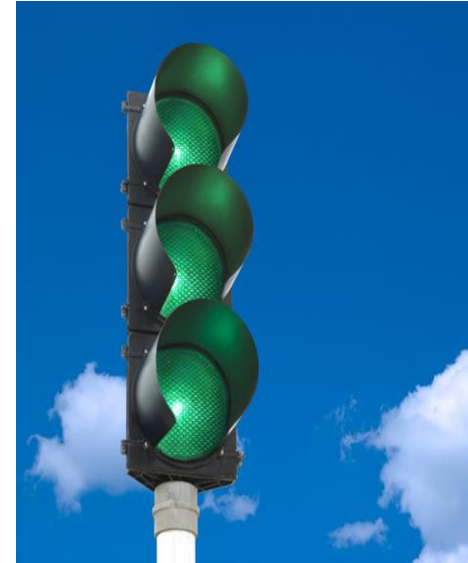
Evolution of 'Engaged' Partnership

- **Community-Based Organization: Nueva Vida**
 - Successful program to address needs and improve QOL of Latina Survivors and Caregivers
 - Trusted relationship with Latino families
- **Academic Partner: Georgetown**
 - Successful prior research with Latina breast cancer survivors
 - Significant interest in intervention research and engaging patients and families



Engaging Community to Engage Patients and Stakeholders

- Understand common goals
 - Improving QOL
- Allow relationships to grow
 - First met in 2007
 - Submitted proposal in 2012
- Recognize patient, family & community expertise and input throughout process
 - Team, Design & Implementation
 - Engagement & Dissemination



Team: Expanded Connections

- Leveraged existing relationships
 - Gilda's Club New York City (NY)
 - Latinas Contra Cancer (CA)
 - SHARE (NY, NY)
- Invited internal and external clinicians, patients, caregivers, researchers and advocates



Design: Nueva Vida Intervention

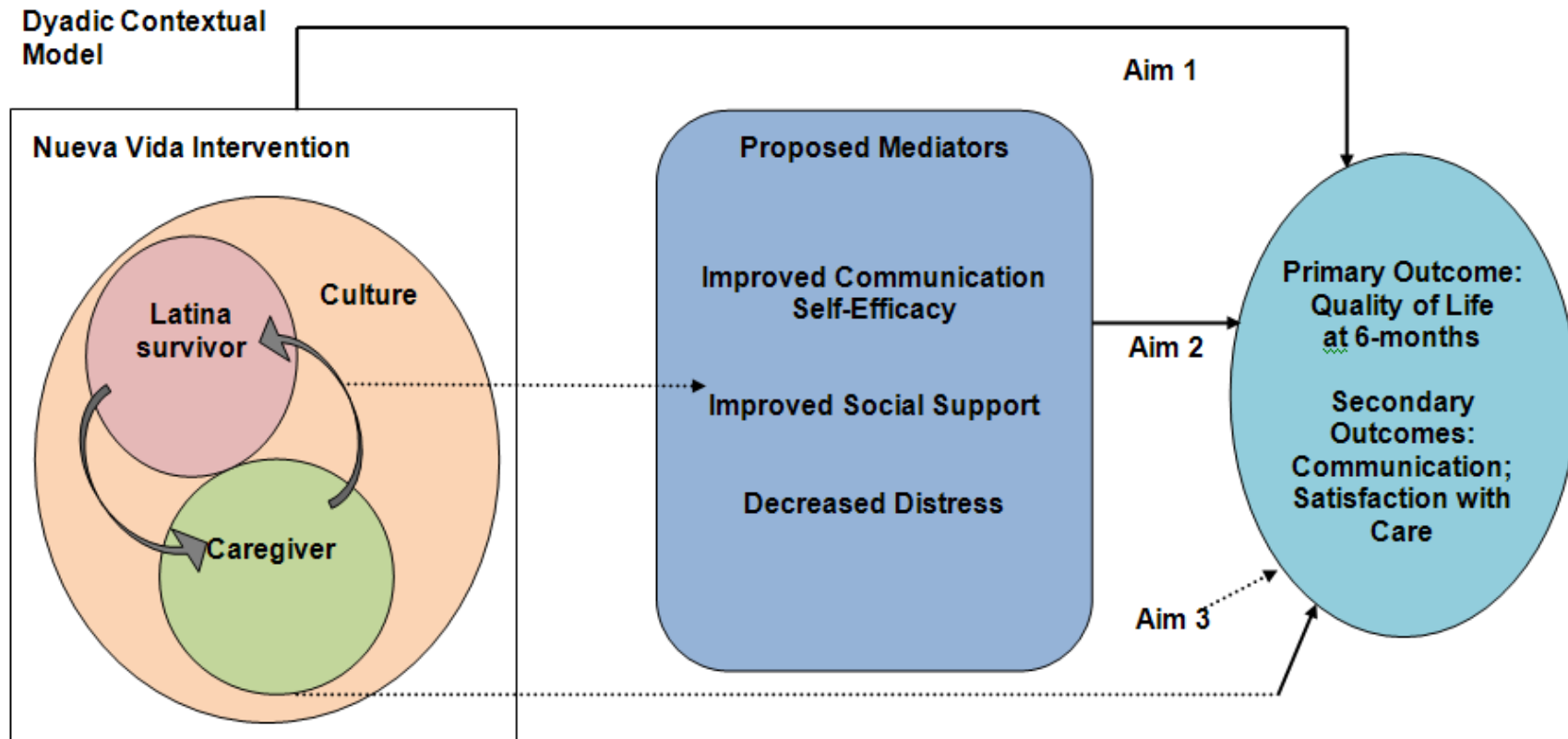


- Comparison (randomized controlled trial) between
 - Nueva Vida Intervention
 - Usual Services
- Focus to improve QOL among
 - Latina breast cancer survivors
 - Caregivers of Latina breast cancer survivors

Design: Communication

- Participant Eligibility (decision = broad)
- Design / Methods
 - Randomized Controlled Trial to fit with PCORI's focus on “comparators”
 - Many phone calls to discuss:
 - Usual Care (decision = typical services offered)
 - Intervention (decision = change delivery schedule)
 - Interventionist Qualifications (decision = broad)
- Outcomes
 - Outcomes of common interest to community organizations and research team (PROMIS)
 - Measurement of intervention mechanisms

Design: Study Aims



Study Description



Beginning of
Study

Baseline
interview

Random
Assignment

Nueva Vida
Intervention

Usual Care
Services

Participants

70
Survivors

70
Caregivers

65
Survivors

65
Caregivers

Implementation: Nueva Vida Intervention



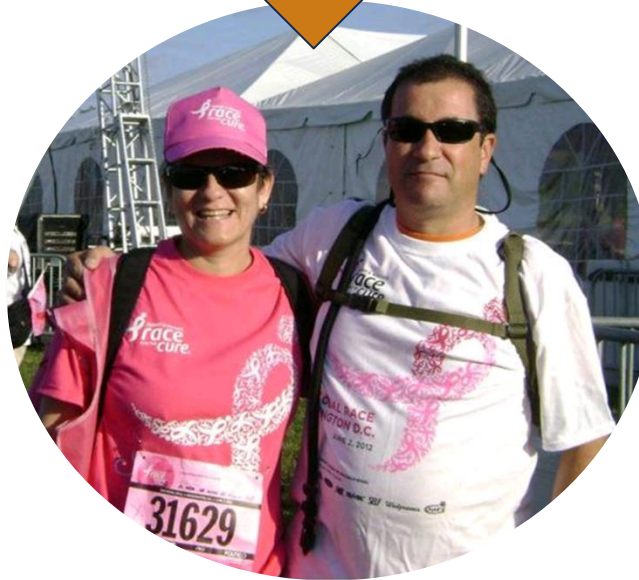
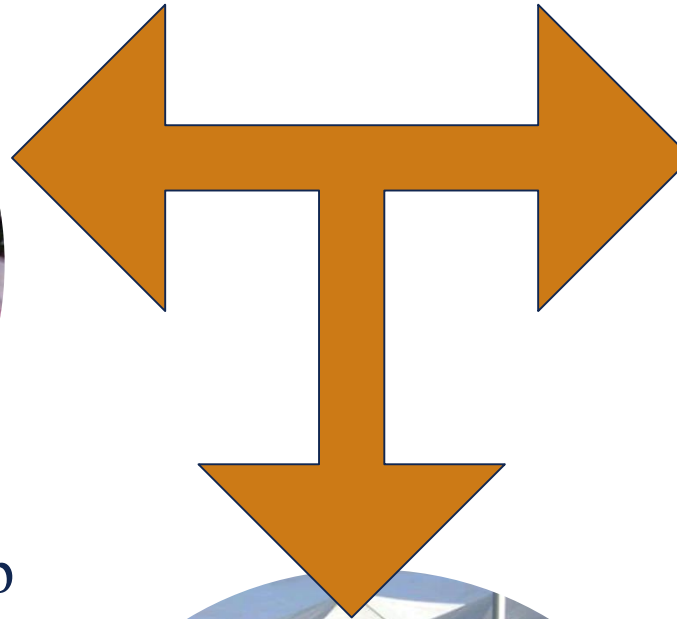
Implementation



Survivor Group



Caregiver Group



Gather together /
Discuss topics

Study Measures: PROMIS®

- Patient Reported Outcomes Measurement Information System
- PROMIS Short-Forms
 - Physical Function
 - Satisfaction with Social Roles
 - Anxiety
 - Depression
 - Fatigue
- Scores are standardized against the US population
 - Mean = 50
 - Standard Deviation = 10

2.4 In the past 7 days...

	Never	Rarely	Sometimes	Often
2.4.a. I felt fearful.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.b. I felt anxious.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.c. I felt worried.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.d. I found it hard to focus on anything other than my anxiety.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.e. I felt nervous.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.f. I felt uneasy.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.g. I felt tense.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.h. My worries overwhelmed me.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.i. I felt like I needed help for my anxiety.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.j. Many situations made me worry.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4.k. I had difficulty calming down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Implementation: “Research Democracy”

8 “talleres” (workshops)

- 2-4 per month
- 5 core topics
- 3 topics: “Research Democracy”

Impact of Cancer on Family (Introduction)*

Stress Management*

Improving Communication*

Spirituality and Cancer*

Balancing Physical and Emotional Needs*

Anger Management

Intimacy after cancer

Trauma and Cancer

Role Changes

Understanding Distress

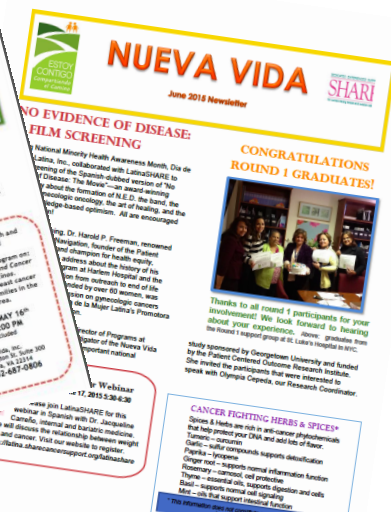
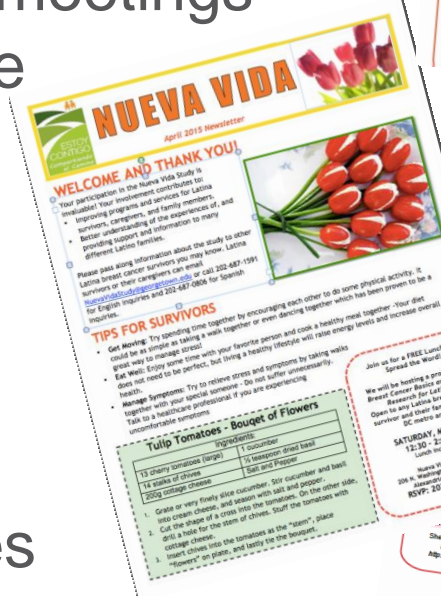
Myths and Cancer

Including Others in Helping Caregivers

Putting Our Lives in Order

Engagement & Dissemination: Equal Input

- Engagement Strategies:
 - Phone calls, scheduling
 - Birthday cards, postcards
 - Twice monthly site check-ins
 - Monthly team phone meetings
 - Annual in person team meetings
 - “Think aloud” technique
 - Polls / Surveys
- Dissemination:
 - Community Meetings
 - Newsletters
 - Webinars
 - Post-Intervention Parties



Results: Participant Characteristics



Recruitment, Enrollment & Retention

- Overall: $242 \text{ active+complete} / 272 = 89\%$
- Retention T1 (n = 100 dyads to date)
 - Registered to T1: $219/375 = 58\%$
 - Randomized to T1: $219/272 = 80.5\%$
- Retention T2 (n = 74 dyads to date; 39 pending dyads)
 - Registered to T2: $169/375 = 45\%$
 - Randomized to T2 (to date): $169/272 = 62\%$
 - Randomized to T2 (complete+pending): $169+73 = 242/272 = 89\%$

Participant Characteristics

N = 136 dyads randomized* 1 withdrew post-randomization

- Intervention (n = 70)
- Usual Care (n = 66)

	Latina Survivors (n = 135)	Caregivers (n = 135) 55 males – 41% 80 females – 59%
% Spanish Survey	93%	82%
% Employed Full-Time	15%	50%
% Less than HS Degree	43%	31%

Results: Countries of Origin

Latina Survivors		Caregivers	
Bolivia	5.8%	Bolivia	3.6%
Columbia	4.4%	Columbia	5.5%
Chile	2.9%	Chile	3.6%
Ecuador	1.5%	Ecuador	3.6%
El Salvador	7.3%	El Salvador	7.3%
Guatemala	7.3%	Guatemala	7.3%
Mexico	23.2%	Mexico	20.0%
Peru	10.1%	Peru	11.0%
Puerto Rico	4.5%	Puerto Rico	3.6%
Dominican Republic	14.5%	Dominican Republic	11.0%
United States	7.3%	United States	18.2%
Other	10.1%	Other	5.5%

Results: Intervention Exit Surveys

[The workshops] give you a new vision and they help you understand the problem so you can face it with a more positive perspective. - Caregiver

[My survivor and I] were able to touch upon certain things we were not comfortable discussing prior to the support group.
- Caregiver

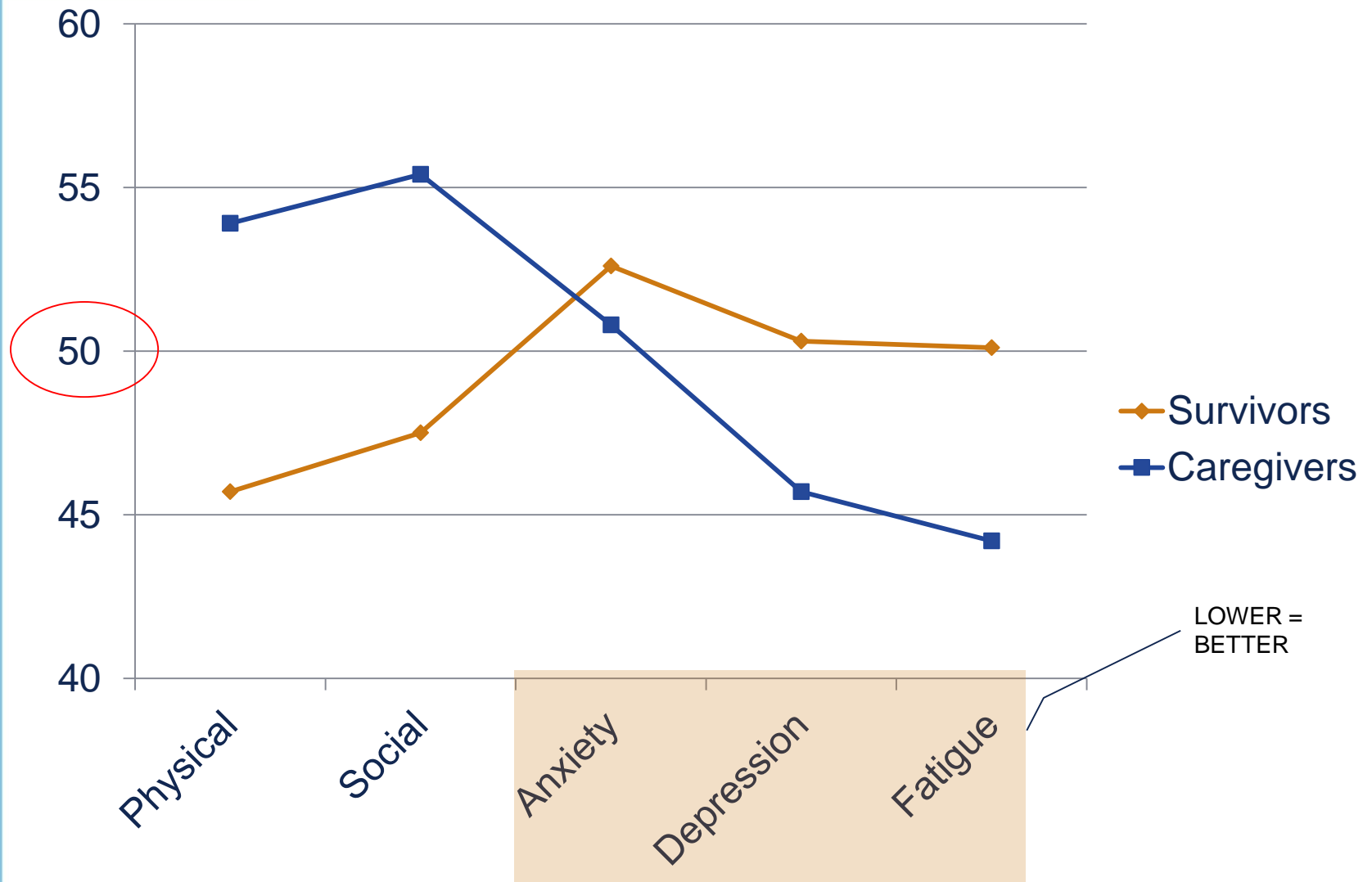


Results: QOL PROMIS Outcomes

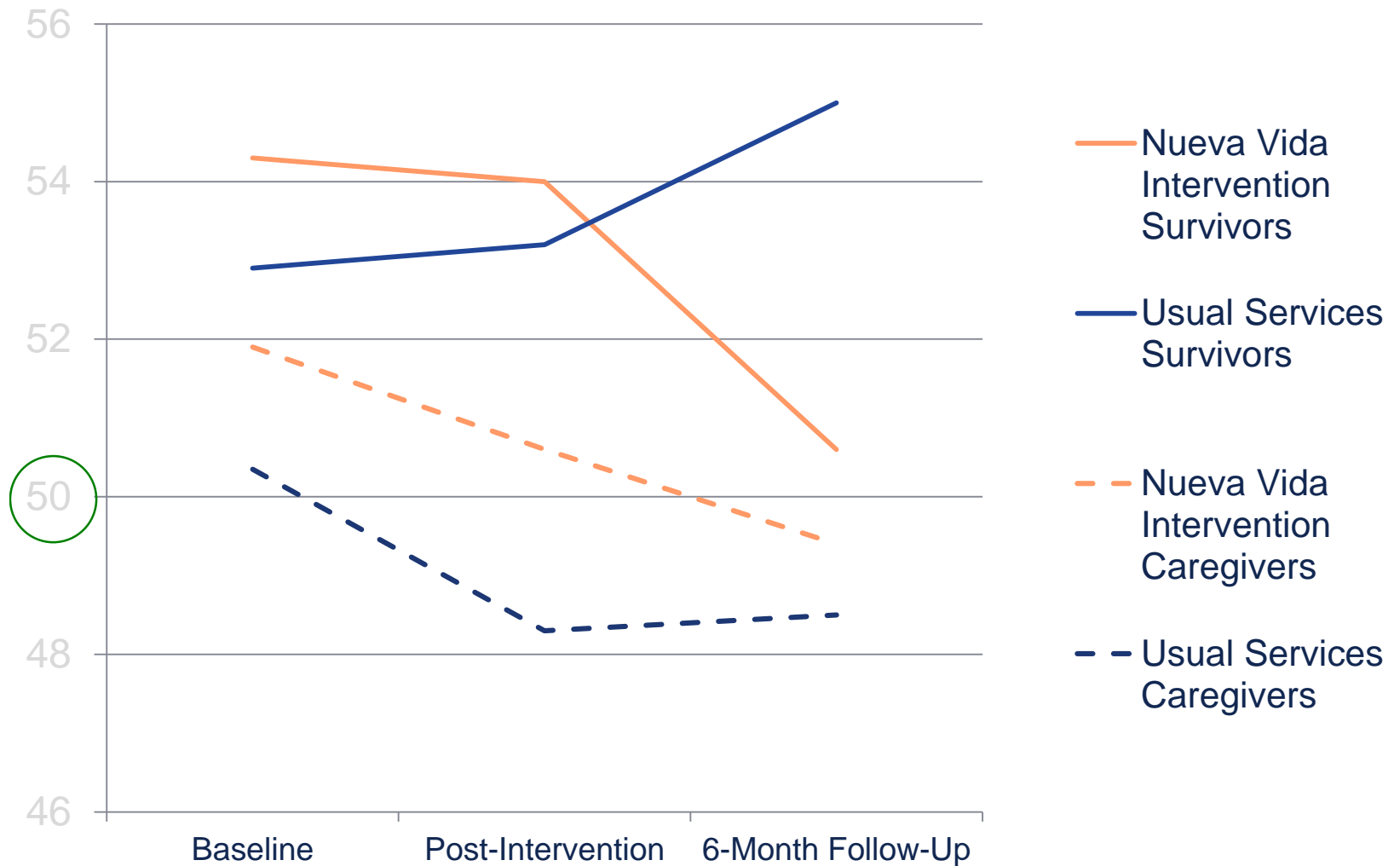
Gilda's Club
NYC!



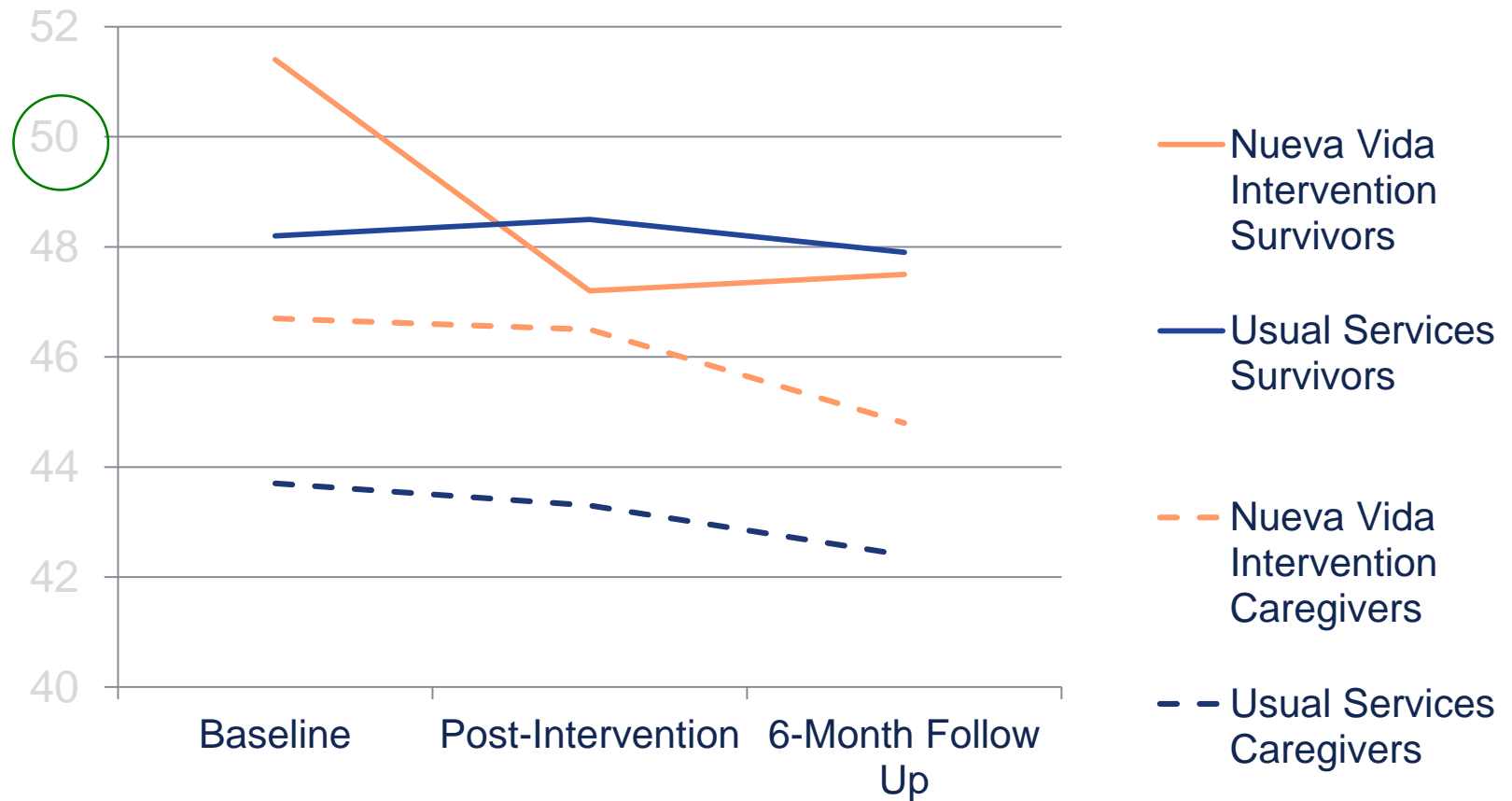
Baseline PROMIS Scores



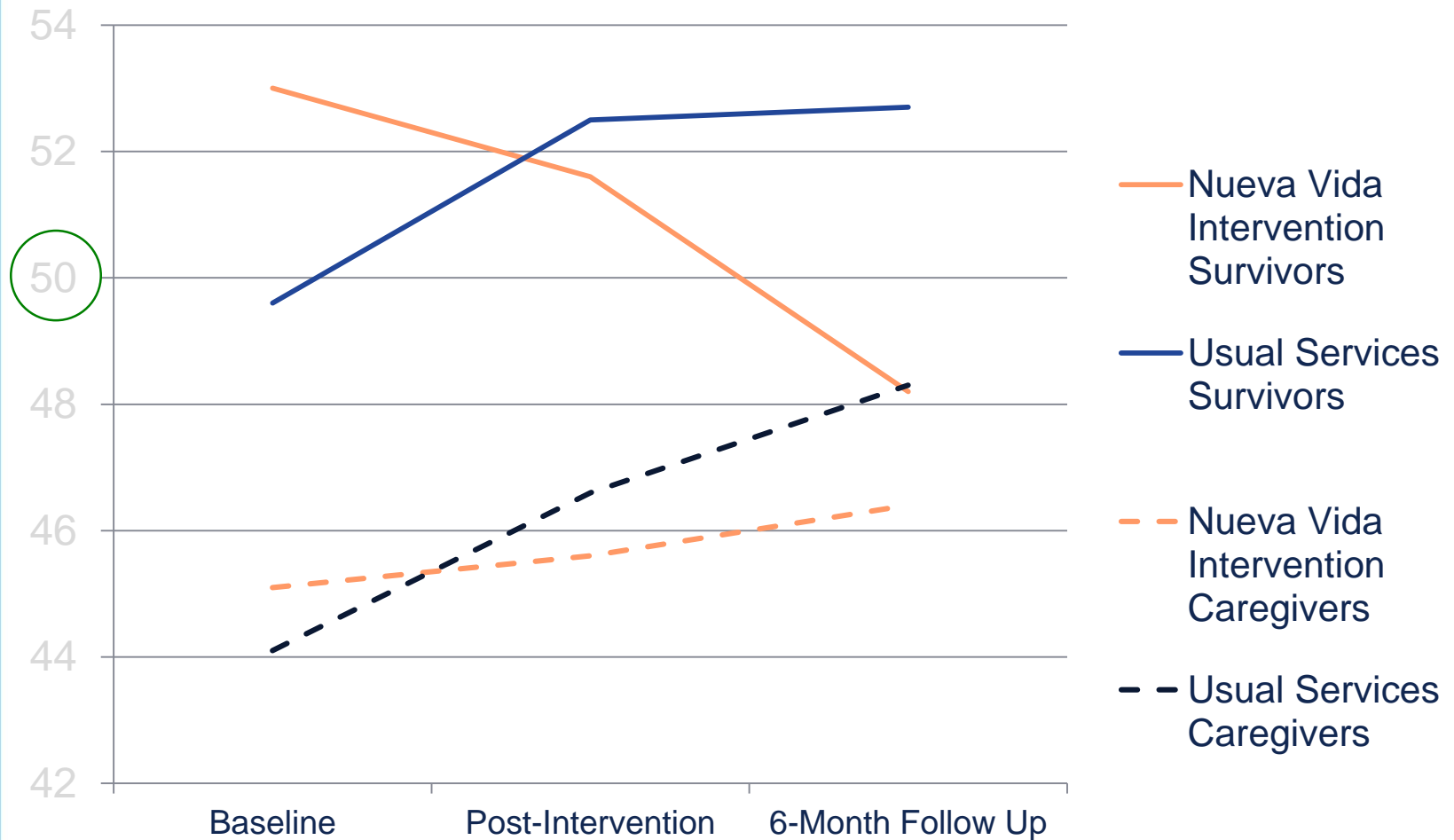
Results: Anxiety



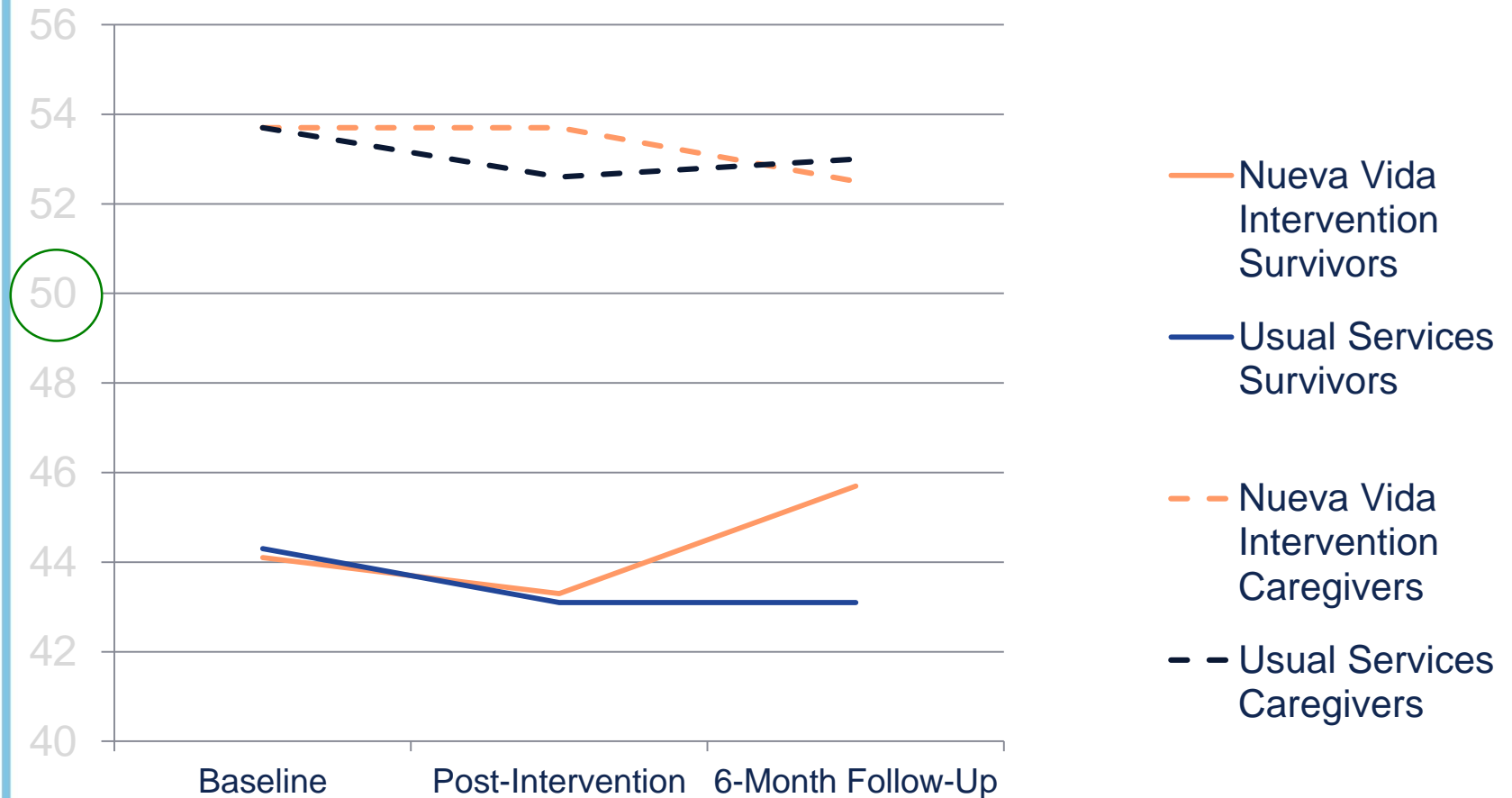
Results: Depression



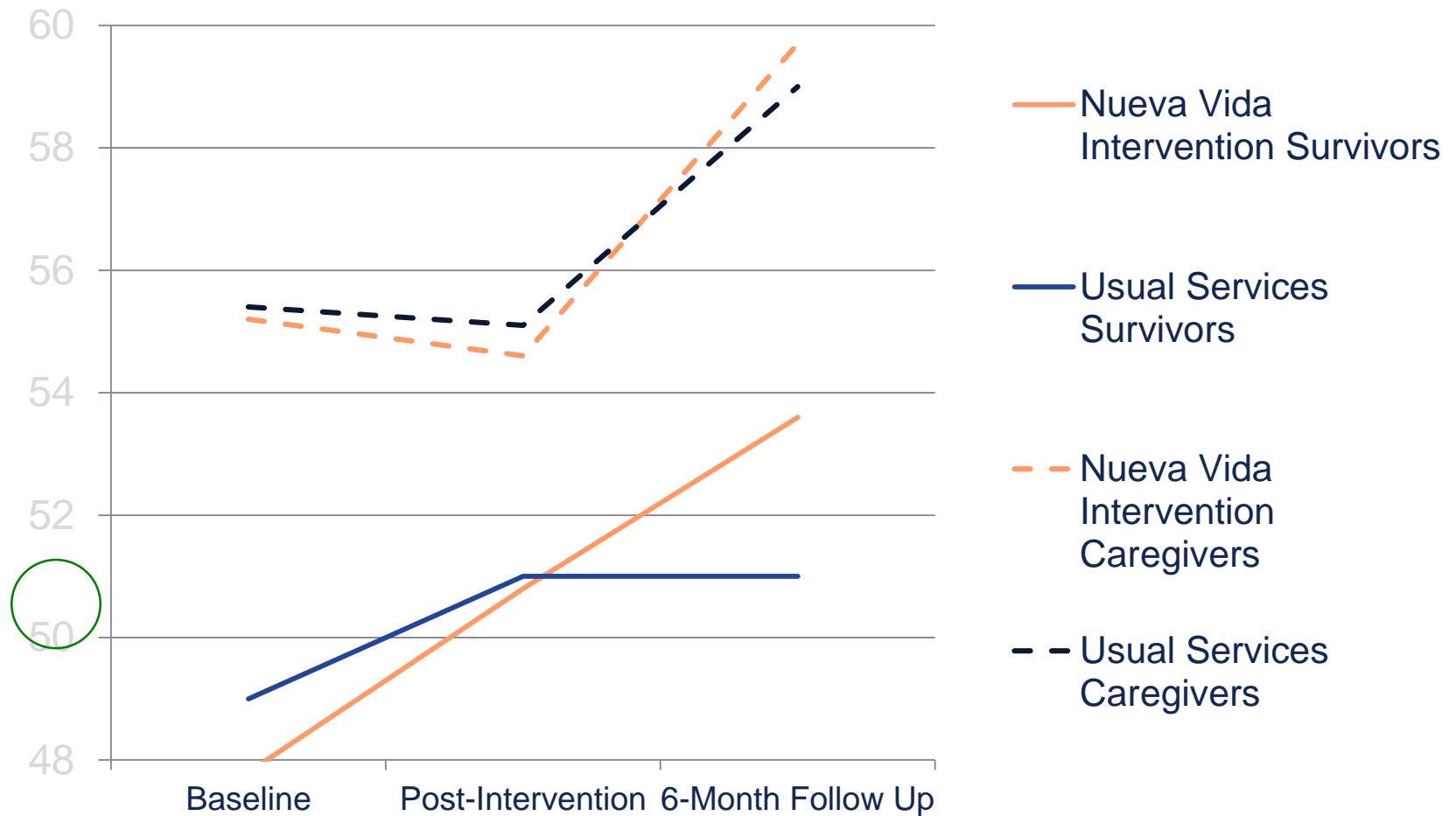
Results: Fatigue



Results: Physical Functioning



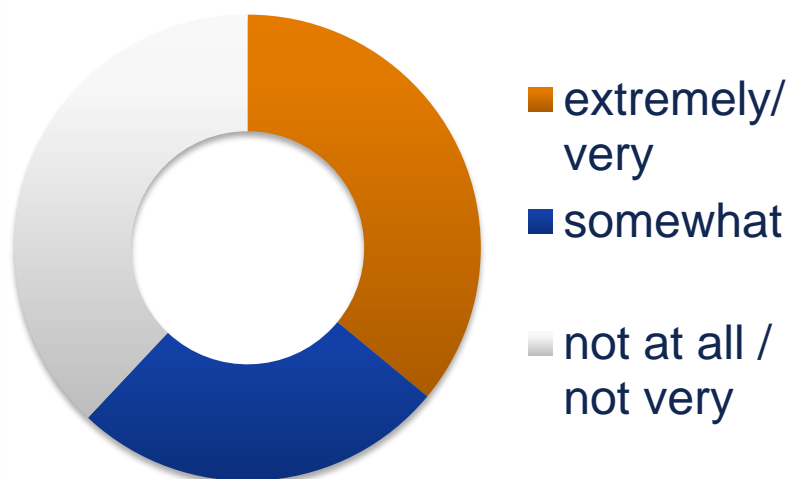
Results: Social Functioning



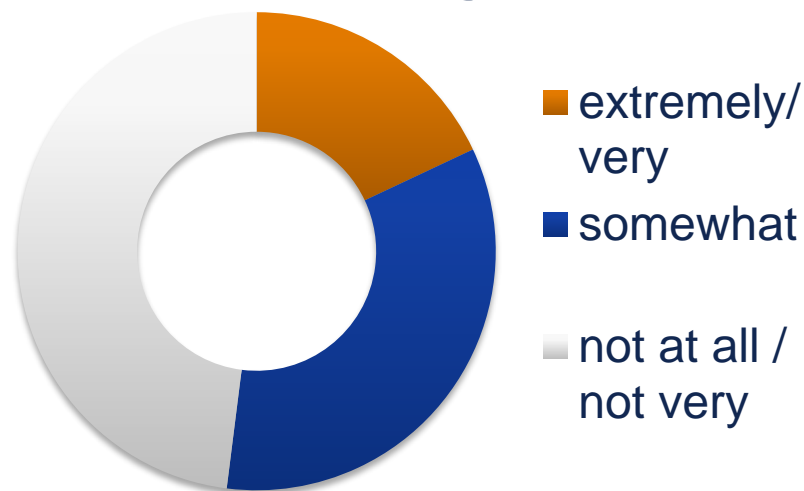
Results: Financial Concerns

How difficult is it for you/your family to meet monthly payments on bills? (Post)

% of Survivors



% of Caregivers



How often do you worry about being able to meet normal monthly living expenses?

Survivors
6 Months

Caregivers
6 Months

Worry All the Time

34%

21%

Sometimes Worry

32%

34%

Rarely/Never Worry

34%

45%



LCC!



Implications, Dissemination & Implementation

- Site Impacts
- Final Results newsletters to participants
- Development of Infographic / key take aways
- Collaborations with other agencies
- Caregiving: National Efforts
 - PAR on caregiving from NCI
 - National Report on Caregiving
- Cancer Support Community's 'Toolkit' Model for dissemination



Thank you!



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CELEBRATING 20 YEARS OF SUPPORT

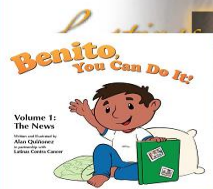
[Learn more >](#)

Read the first ever Children's Cancer book based on Latino testimonial - Benito Volume 1

ENGLISH / ESPAÑOL MUSIC ON - OFF



EDUCATION
NAVIGATION
AND SUPPORT
FOR THE UNDERSERVED
LATINO POPULATION
AROUND ISSUES
OF CANCER



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LATINAS CONTRA CANCER is raising awareness about cancer in the Latino community, increasing access to quality care, working to decrease mortality and improving the quality of the health care experience. We do this by offering support services and resources for the Latino cancer patient and their family; collaborate with other small agencies to provide education and outreach

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Never Gives Up

A Support Network for Latin@s with Cancer and their Families

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DEDICATED EXPERIENCED SUPPORT

SHARE

for women facing breast and ovarian cancers

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SHARE CAREGIVER CIRCLE



CAREGIVERS NEED SUPPORT, TOO

We now offer services to help meet the needs of caregivers. [Get support.](#)

Georgetown University:

Roxanne Jensen
Jeanne Mandelblatt
Vanessa Sheppard
Stacey Kaltman
George Luta
Christina Rush
Adriana Serrano
Tania Lobo
Neha Rajpal
Maxie Blasini
Charlene Kuo

Nueva Vida:

Astrid Jimenez (PI)
Claudia Campos
Maria Eugenia del Villar
Alma Hamar

Gilda's Club NYC:

Migdalia Torres (PI)
Carolina Hoires
Awilda Torres
Lily Safani

SHARE:

Ivis Febus Sampayo (PI)
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Maria Gloria Elliott
Barry Jacobs
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Robert Warren
Regina Hampton
Monique Perret-Gentil
Wanda Lucas

Other Partners:

Lombardi Breast Cancer
Patient Advocacy Committee

Data Safety Monitoring:

Alfiee Breland-Nobel
Filipa Lynce
Georgeen Newland
Floencia Gonzalez





Kristi.Graves@georgetown.edu

Major Milestones

Interventionist Training
3/2014

Recruitment Begins
6/2014

Round 1
11/2014

Recruit over 100 dyads! 5/2016
6/2015

Round 2
5/2015

Round 3
10/2015

End of Study
Celebrations

2014

2015

2016



LCC Group 3

Future Analyses / Implications

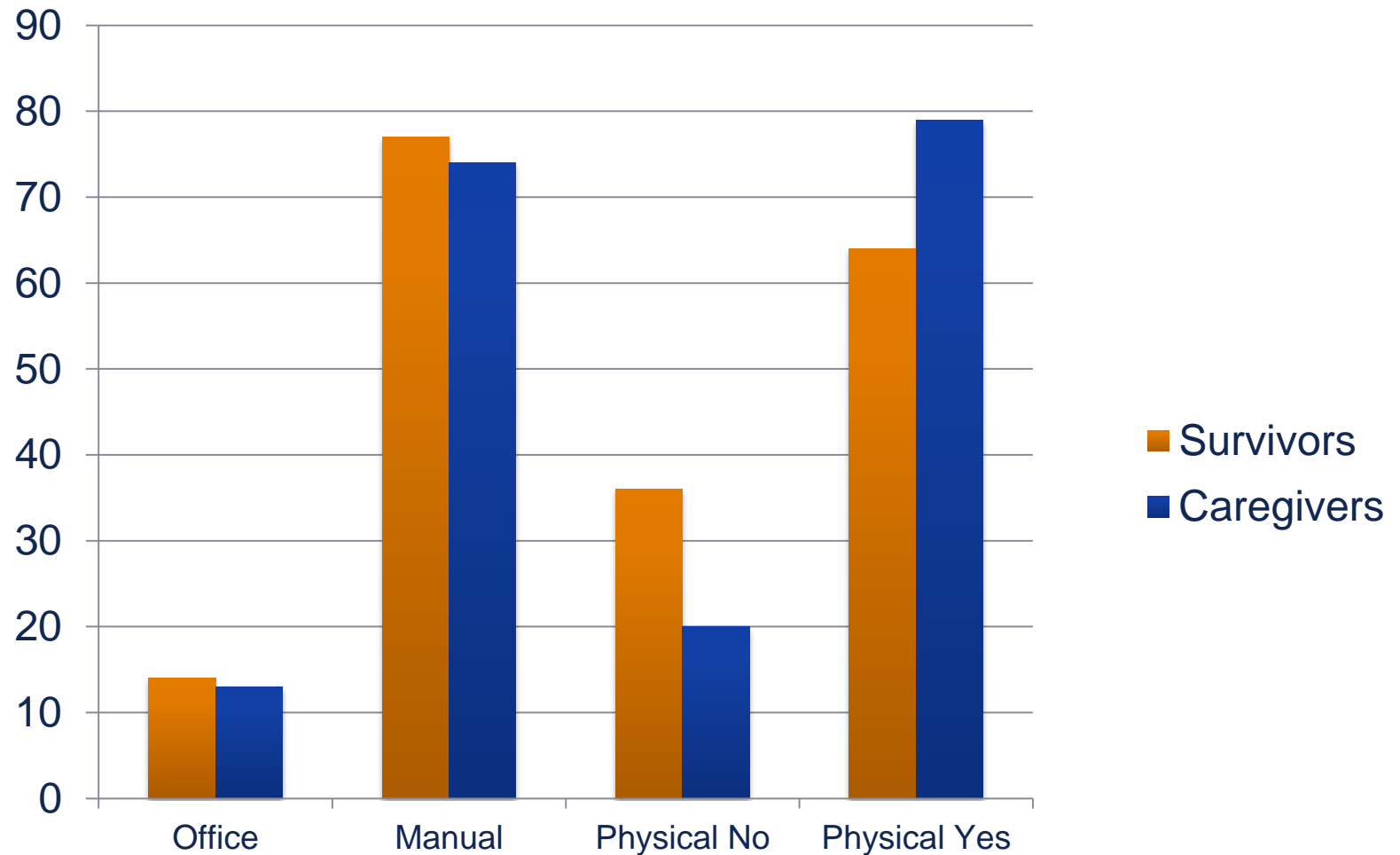
- Dyadic Analyses (S-C) on main outcomes controlling for:

Stage of Breast Cancer	Age (both)	Time since diagnosis
Years in US / Acculturation	Education	Income

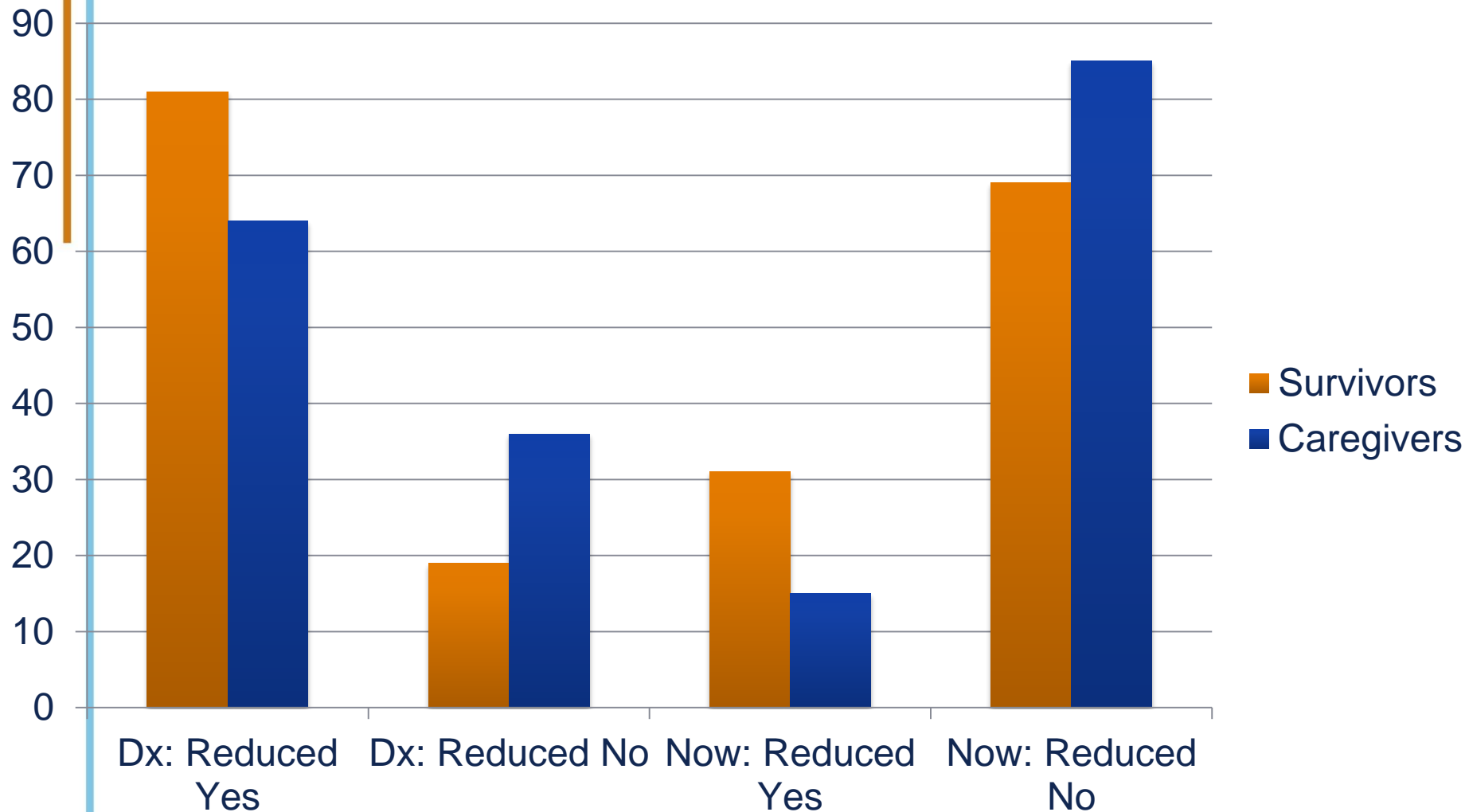
- SubAnalyses

Men (40% of caregivers)	Survivor Region of Origin:	Caregiver Region of Origin:
Caregiver Relationship	Mexico (25%) Central America (18%) South America (24%) Caribbean (19%) US (7%) Other (9%)	Mexico (23%) Central America (17%) South America (22%) Caribbean (21%) US (13%) Other (2%)

Results: Employment Type



Results: Impact on Work Reduced Hours



Benefits of Engagement

- Short-term:

- Greater relevance
- More likely to address true needs
- Increased awareness of a community's:
 - Strengths / Expertise
 - Services / Resources
- Greater proposal appeal

- Long-term:

- Increased capacity
- Greater likelihood for dissemination / impact
- Expanded (and strengthened) partnerships



Challenges to Engagement

- Implementation subtleties / less “internal validity”?
 - Greater external validity / real-world research
 - Rich diversity in patients and caregivers
- Ready to listen carefully and share decisions?
 - Greater salience to patients, family & community
 - Ready to provide infrastructure support and training as needed?
 - Additional effort for engaging caregivers
 - Proposal needs (biosketches, budgets)
 - Research basics, Human Subjects
 - Paperwork procedures



What was one (or more) highlight of your experience being part of this study?

- The team made everything flow smoothly. It is a very collaborative environment that is supportive and flexible, all of which helps excel in performance and duties
- Hearing from the participants how much these meetings supported and helped them and watching my team in action-always going the extra mile, making me proud!



Final Wrap-Up, Staying Connected



Discussion

Lunch

We will resume at 1: 00 PM ET



Addressing Disparities Program Updates: Targeted Portfolio and Pragmatic Clinical Studies Portfolio

Cathy Gurgol, MS

Program Officer, *Addressing Disparities*

Ayodola Anise, MHS

Program Officer, *Addressing Disparities*

Parag Aggarwal, PhD

Senior Program Officer, *Addressing Disparities*



Addressing Disparities Program Updates: Targeted Portfolio and Programmatic Clinical Studies Portfolio

- **Cathy Gurgol, MS**
 - Obesity Treatment Options Set in Primary Care for Underserved Populations
- **Ayodola Anise, MHS**
 - Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations (PI: Elliot Israel, Brigham and Women's Hospital)
 - Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma
 - Testing Multi-Level Interventions to Improve Blood Pressure Control in Minority Racial/Ethnic, Low Socioeconomic Status, and/or Rural Populations
- **Parag Aggarwal, PhD**
 - Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural FQHCs (PI; John Fortney, University of Washington)
 - Management of Care Transitions for Emerging Adults with Sickle Cell Disease



Obesity Treatment Options Set in Primary Care for Underserved Populations

Cathy Gurgol, MS

Program Officer, *Addressing Disparities*



Obesity Treatment Options Set in Primary Care for Underserved Populations

- Recently Medicare began coverage for intensive behavioral therapy for obesity delivered in primary care practices by primary care physicians, physician's assistants, nurse practitioners.
- This delivery model is not evidence-based.
- Targeted PCORI Funding Announcement awarded two comparative effectiveness trials to garner evidence about the delivery of intensive behavioral therapy for obesity in primary care practices that could influence policy-makers (\$20 million for two 5-year trials).
- Each trial is taking place in primary care practices and delivers evidence-based intensive behavioral therapy compared to the obesity treatment described by Medicare's coverage policy.



Decisional Dilemma: Obesity Treatment

Primary Care Practice: *We want to provide an effective behavioral weight loss treatment to our patients. Should the PCPs deliver the treatment or should it be delivered by another type of provider or obesity specialist. The PCP is convenient for patients, but there are many time constraints and they may not be trained in behavioral obesity treatment.*



Midwestern Collaborative for Treating Obesity in Rural Primary Care (PI: Christie Befort, PhD; University of Kansas Medical Center)

- **Research Question:** Is intensive behavioral treatment for obesity delivered in a patient-centered medical home (PCMH) or Disease Management (DM) setting more effective for weight loss than fee-for-service obesity counseling delivered by a PCP?
- **Comparator:** PCMH and DM models compared to fee-for-service (Medicare model)
- **Design:** Cluster RCT, pragmatic
- **Sample:** Target N=1440 participants, 36 sites
- **Population:** Rural
- **Outcomes:** Weight loss, QOL, BP, sleep quality, stress, physical activity, diet, satisfaction, process measures



Midwestern Collaborative for Treating Obesity in Rural Primary Care (PI: Christie Befort, PhD; University of Kansas Medical Center)

- **Highlights:**
 - Project is ahead of recruitment projections (N=505 as of 10/2016)
 - Pragmatic model
 - Excellent site engagement and communication models
 - Working on manuscript describing site recruitment
- **Potential Impact**
 - Increase reach of behavioral intervention in rural population, which has limited access to obesity treatment outside of primary care.



The Louisiana Trial to Reduce Obesity in Primary Care (PI: Peter Katzmarzyk, PhD; Pennington Biomedical Research Institute)

- **Research Question:** Will patients who receive a high-intensity, health literacy-appropriate and culturally adapted lifestyle intervention delivered by health coaches embedded in a primary care setting have greater and clinically significant percent reductions in body weight compared to the obesity treatment covered by Medicare?
- **Comparator:** intensive behavioral obesity treatment delivered by health coaches in primary care practices compared to Medicare model
- **Design:** Cluster RCT, pragmatic
- **Sample:** Target N=1080 participants, 18 sites
- **Population:** low-income, African American
- **Outcomes:** Weight loss, QOL, BP, stress, physical activity, satisfaction diet, process measures



The Louisiana Trial to Reduce Obesity in Primary Care (PI: Peter Katzmarzyk, PhD; Pennington Biomedical Research Institute)

- **Highlights:**
 - Project is meeting recruitment projections (N=309 as of 10/2016)
 - Excellent site engagement
 - Published manuscript describing focus groups: Perceptions of Obesity Treatment Options Among Healthcare Providers and Low-Income Primary Care Patients
- **Potential impact:**
 - Obesity treatment options delivered in primary care have resulted in limited success, perhaps due to the low intensity of interventions. This intervention is economical and scalable to large patient populations.



Discussion

Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations (PI: Elliot Israel, Brigham and Women's Hospital)

Ayodola Anise, MHS

Program Officer, *Addressing Disparities*



Decisional Dilemma: Asthma

African American or Hispanic/Latino with chronic asthma: I would like to better manage my asthma. Should I continue with my regular care or participate in a research study that is tailored to my needs?



Pragmatic Clinical Study: Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations (PI: Elliot Israel)

- **Intervention:** Patient-Activated Reliever-Triggered ICS (PARTICS) approach: Use of ICS + short-acting beta-agonist (SABA) reliever only when asthma symptoms are present plus provider-educated standard of care
- **Comparators:** Daily use of ICS + long-acting beta-agonist (LABA) plus provider-educated standard of care (regardless of presence of asthma symptoms)
- **Study Design:** Randomized Control Trial
- **Sample Size/Population:** 1200 African American and Hispanic/Latino patients between the ages of 18-75 years with asthma
- **Outcomes:** Asthma exacerbations (primary); Asthma control, preference-based quality of life, days lost from work or school (secondary)
- **Potential Impact:** This study has strong potential to inform National Asthma Education Prevention Program guidelines
- **Progress to Date:**
 - Identified and signed contracts with 14 participating sites
 - Developed and implemented training on study protocol with 4 vanguard sites
 - Engaged national and regional stakeholders to join study advisory board



Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

Ayodola Anise, MHS

Program Officer, *Addressing Disparities*



Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

- PCORI issued the funding announcement with the goal of reducing asthma disparities for African Americans and Hispanics/Latinos by improving patient and clinician adherence to the NAEPP guidelines.
- **Studies funded:** 8 projects for \$23.2 million (2013)
- **Interventions:** Are diverse, tailored, and test multi-component interventions at the community, home, and health system levels with proven efficacy
- **Outcomes:** Asthma control, asthma-related QOL, missed days of work or school, medication adherence, lung function, exacerbations
- **Progress to date:**
 - **6 projects** have completed recruitment and all studies to be completed by December 2017



Alignment of Asthma Studies with NAEPP Guidelines

- NAEPP guidelines emphasize multi-level, multi-component interventions for improving asthma outcomes with approaches to address:
 - Clinician education
 - Patient education
 - Control of environmental factors
 - Medications
- Interventions from the 8 studies align with approaches and strategies recommended in the NAEPP guidelines



Interventions Focused on Clinician Education

- **Educating clinicians** can promote or reinforce knowledge and attitudes associated with appropriate asthma care.
- 4 studies address clinician education
- **Study Example:** *Guidelines to Practice (G2P): Reducing Asthma Health Disparities through Guideline Implementation (PI: James Stout)*
 - 2x2 factorial design, RCT with 550 African American and Hispanic/Latino patients 5-75 years
 - Compares enhanced clinic care and CHW home visits nested within a health plan and provider education intervention.
 - All clinicians receive training using the Provider Asthma Care Education (PACE) curriculum
 - A subset of clinicians participate in small group case-based learning to review the guidelines and receive training grounded in patient centered approaches (e.g., motivational interviewing, participating in shared decision making)



Interventions Focused on Clinician Education (cont.)

- **System and clinical decision supports** prompt guideline-based care and address the organization and delivery of asthma care
- 4 studies address use of supports (e.g., EHR enhancements, audit and feedback, care teams, modification to notes, care plans, orders).
- **Study Example: Imperial County Asthma CER Project (PI: John Elder)**
 - 2x2 factorial design, RCT with 400 Hispanic/Latino children 6-17 years.
 - Comparing a family and clinic intervention nested in a community intervention
 - Clinics have modified staffing and workflow and use asthma educators/case managers.
 - System changes include asthma care templates that can be tailored and prompts to support clinician decision making, sharing of educational messages, treatments, and behavioral recommendations.



Patient Education

- **Patient education in the clinic or ED** presents an opportunity for clinicians to build rapport, establish a partnership, and discuss and agree to a treatment plan.
- All 8 studies address patient education in the clinic or ED.
- ***Study Example: Clinic-Based vs. Home-Based Support to Improve Care and Outcomes for Older Asthmatics (PI: Alex Federman)***
 - 3 arm RCT with 405 African American and Hispanic/Latino patients 60+ years of age.
 - Compares clinic-based support by an asthma care coach, home-based self-management by CHW, and usual care.
 - Asthma care coaches in the clinic provide care coordination and intense self-management support to address barriers, discuss medication adherence and inhaler techniques, provide patient education, and review Asthma Action Plans.



Patient Education (cont.)

- **Patient education within the home** has the ability to address individual needs over a period of time and where people live.
- CHWs can provide education on medication adherence, environmental remediation, and Asthma Action Plans
- 6 studies address patient education in the home
- ***Study Example: Using Information Technology to Improve Access, Communication and Asthma in African American and Hispanic /Latino Adults*** (PI: Andrea Apter)
 - 2 arm RCT with 300 African Americans and Hispanics/Latinos 18+ years
 - Compares patient portal web-based communication tool of the EHR with and without in-home CHW-led patient training
 - CHWs train patients on Patient Portal, which offers web-based access to clinicians and practices and allows patients to make appointments, refill medications, and communicate directly with clinicians.



Control of Environmental Factors

- CHWs can provide education on environmental factors that trigger asthma and develop remediation plans with patients
- 5 studies address home/indoor environmental factors (e.g., triggers and inhalant allergens)
- 1 study addresses outdoor pollutants and irritants
- **Study example:** *The Houston Home-based Integrated Intervention Targeting Better Asthma Control (HIIT-BAC) for African Americans (PI: Winifred Hamilton)*
 - 2 arm RCT with 300 African American patients 18+ years
 - Compares enhanced clinic care to a CHW home-based asthma control and environmental intervention
 - CHWs and environmental hygienists assess the home environment and provide potential strategies to mitigate triggers



Use of Long-term Control and Quick Relief Medication

- Since the NAEPP guidelines were updated in 2007, other newer guidelines recommend as needed use of inhaled corticosteroids (ICS) with asthma symptoms
- Studies have shown that this approach is effective, but they have been small trials with few racial/ethnic minorities
- 1 study addresses as needed use of ICS
- **Study example:** Preference and Effectiveness of Symptom-Based Adjustment of ICS Therapy in African American Children (PI: Kaharu Sumino)
 - 2 arm RCT with 200 African American children 6-17 years
 - Compares symptom-based adjustment of ICS, where parent/patient controls their medication usage based on their daily symptoms, to guideline-based adjustment of ICS



Alignment of Studies and Potential Clinical Impact

- Studies test strategies to improve patient and clinician adherence to guidelines and approaches to tailoring interventions that meet the needs of patients.
- All studies have patient partners, lending to interventions that are more relevant to and meet the needs of patients.
- Interventions may be more likely to be implemented in practice, as other stakeholders have been actively engaged in the conduct of the studies.
- 4 studies have agreed on common clinical, patient-centered, and patient-reported outcomes that could lead to the aggregation of data and pooling of results.
- Understanding which strategies and combination of strategies (e.g., decision tools in the EHR, use of care plans, patient education in the home, tailored Asthma Action Plans) support care for asthma could help to reduce disparities.



Testing Multi-Level Interventions to Improve Blood Pressure Control in Minority Racial/Ethnic, Low Socioeconomic Status, and/or Rural Populations

Ayodola Anise, MHS

Program Officer, *Addressing Disparities*



Decisional Dilemma: Hypertension

African American with hypertension:

I have hypertension and worry about my risk for heart disease. Should I continue with my regular care? Or should I participate in a study where I receive self-management support from a coach as a way to improve my blood pressure and prevent other problems? I'm worried about how much time this will take, but what I'm getting now may not address my needs.



Addressing Disparities Targeted Project: Hypertension

- **Announcement:** Testing Multi-Level Interventions to Improve Blood Pressure Control in Minority Racial/Ethnic, Low Socioeconomic Status, and/or Rural Populations in collaboration with the National Institute for Health (NIH).
- **Partnership:** The Hypertension Disparities Reduction Program Partnership (HDRPP) is a research partnership with NHLBI, NINDS, and PCORI with funds provided by PCORI to NIH.
 - HDRPP funded two comparative effectiveness trials for \$23.5 million (2015).
 - Partnership allows collaboration and alignment of outcomes among studies.



Collaboration to Improve Blood Pressure in the U.S. Black Belt: Addressing the Triple Threat (Co-PI's: Monika Safford & Andrea Cherrington)

- **Intervention:** This study will compare the effectiveness of two practical approaches to achieving better blood pressure control among African Americans in the Black Belt region.
- **Comparators:** (1) usual care plus a free online patient education program, (2) peer coaching plus education, (3) practice facilitation plus education, and (4) both peer coach and practice facilitation plus education.
- **Study Design:** Cluster-randomized, 2x2 factorial designed pragmatic trial.
- **Sample Size/Population:** 2,000 African American patients with uncontrolled hypertension from 80 practices (25 patients/practice).
- **Outcomes:** Improvement in blood pressure control (<140/90 mm Hg) between baseline and the end of one year of follow-up (primary); group mean BP differences between baseline and follow-up, quality of life, patient satisfaction, healthcare utilization, and provider and staff satisfaction (secondary).



Collaboration to Improve Blood Pressure in the U.S. Black Belt: Addressing the Triple Threat (Co-PI's: Monika Safford & Andrea Cherrington)

- **Potential Impact:** Study will be the first to compare the effectiveness of alternative approaches to hypertension management among a low SES African American population in a rural setting – the Black Belt region. If study findings are positive, it could result in more scalable interventions for this region.
- **Progress to Date:**
 - Successfully completed the first year developmental phase, including:
 - Programmatic and engagement milestones.
 - Developed interventions with stakeholder input.
 - Developed and obtained DSMB approval on study protocol.
 - Obtained IRB approval and piloted study elements (e.g., feasibility of recruitment).
 - Discussions are underway regarding modification of enrollment criteria that identifies most at-risk patients.
 - Developing and implementing practice readiness assessment to identify sites that have capacity and capability to participate in practice facilitation.



Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities (Co-PI's: Lisa Cooper & Jill Marsteller)

- **Intervention:** The study will measure and document specific components of a collaborative care intervention and community health worker (CHW) intervention to improve patient blood pressure control and reduce disparities in hypertension.
- **Comparators:** (1) enhanced standard of care, (2) clinic-based collaborative care with a stepped approach that includes community-based contextualized care delivered by a CHW, specialist consultation, or both, to reduce hypertension risk factors in diverse, high-risk patient groups.
- **Study Design:** Prospective cluster-randomized trial.
- **Sample Size/Population:** 1,890 underserved patients receiving care at 30 community-based primary care practices (63 patients/practice).
- **Outcomes:** Blood pressure control (<140/90 mm Hg) and systolic BP at 12 and 24 months (primary); attainment of self-determined goals related to self-management behaviors, health related quality of life, depressive symptoms, patient assessment of care for chronic conditions, patient ratings of trust, HTN knowledge and attitudes, and patient ratings of intervention (secondary).



Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities (Co-PI's: Lisa Cooper & Jill Marsteller)

- **Potential Impact:** Study will show how the use of more collaborative, specialist/CHW care has potential to reduce hypertension and other major CVD risk factors in underserved, minority populations living in urban and rural areas. Health systems will learn about best approaches to reduce hypertension and other CVD risk factors among patients with risks for disparities.
- **Progress to Date:**
 - In development year:
 - Engaged patients and stakeholders (e.g., payers, health systems) using principles of community-based participatory research.
 - Developed an DSMB approved evidence-based, pragmatic intervention protocol.
 - Identified and secured letters of agreement with 5 health care systems.
 - Conducted pilot study (e.g., review of surveys, ability to recruit and accurately measure patient BP).
 - Received IRB approval.



Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural FQHCs (PI; John Fortney, University of Washington)

Parag Aggarwal, PhD

Senior Program Officer, *Addressing Disparities*



Decisional Dilemma: Complex Psychiatric Disorders

Rural patient with PTSD or Bipolar Disorder:

I would like to manage my condition better. Should I continue with my current treatment plan or participate in a study that incorporates telepsychiatry collaborative care and enhanced referrals? If telehealth doesn't work, could I try phone-psychiatry? Both programs are time intensive and may be too modern to meet my current needs or advanced to function in my home.



Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural Federally Qualified Health Centers (PI: John Fortney)

- **Intervention:** To treat or facilitate the referral of patients with complex mental health disorders from low-income, rural populations to special mental health treatment using telemedicine technology.
- **Comparators:** Collaborative Care Model (adapted to support PCPs in the management of PTSD and BD patients) and Telepsychiatry Referral Model (virtually located but not integrated with primary care services).
- **Study Design:** Randomized Control Trial
- **Sample Size/Population:** 1,000 PTSD or Bipolar Disorder patients from 15 Community Health Centers across three states: Arkansas, Michigan and Washington.
- **Outcomes:** Health related quality of life, access to care, patient activation, satisfaction with care, and medication adherence



Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural Federally Qualified Health Centers (PI: John Fortney)

- **Potential Impact:** This study will be the first to compare two alternative approaches to managing complex mental health problems in rural, primary care settings where referral to off-site specialty care is often not a feasible option.
- **Progress to Date:**
 - Project initiated on **January 1, 2016**.
 - Large, in-person kick-off meeting held on **April 25, 2016**.
 - The **Community Advisory Board (CAB)** and **Policy Advisory Board (PAB)** have been actively engaged in adapting survey scales, and contributing to the overall study design and dissemination plan. The team has taken feedback from the CAB to create **a web-based option for completing the hour-long baseline survey**.
 - EHR licensures have been obtained for clinicians to chart across health systems.
 - Dr. Fortney has **initiated site visits** and trainings for his staff.
 - Recruitment is on track to begin **October 2016**, two months ahead of the scheduled start date.



Management of Care Transitions for Emerging Adults with Sickle Cell Disease

Parag Aggarwal, PhD

Senior Program Officer, *Addressing Disparities*



Management of Care Transitions for Emerging Adults with Sickle Cell Disease

- **Research Question:** What is the comparative effectiveness of established transition coordination models for emerging adults with SCD transitioning from pediatric to adult care?
- **Population:** Emerging Adults (16-25 years of age) with SCD.
- **Interventions and Comparators:** Efficacious or commonly used transition coordination interventions
 - An appropriate comparator may be usual care or standard of care
 - Evidence of efficacy in other diseases and transition models may be used
- **Outcomes:** Health related quality of life; Patient activation/self-management; Number of hospitalizations; Number of days hospitalized; Measures of emergency department use
- **Study Design:** Cluster RCT
- **Settings:** Outpatient settings
- **Timing and Research Commitment:** 5-year, \$25M; Fund up to 3 studies



Sickle Cell – LOIs and Next Steps

- Pre-announcement and Town Hall indicated high level of interest
- LOIs received on September 14, 2016
- Reviewed by two members of Program Staff
- On-the-border decisions were discussed internally
- Final feedback to applicants sent October 7, 2016
- Applicant Town Hall scheduled for November 3, 2016

Action	Date
Targeted PFA Released—Online System Opens	August 15, 2016
Letter of Intent Due	September 14, 2016
Application Deadline	December 19, 2016
Merit Review	March 2017
Board of Governors Vote to Approve Awards	Summer 2017



Discussion

Topic Brief Discussions: Sleep Apnea Eye Drops vs. Laser Surgery

Cheryl Pegus, MD, MPH, Chair

Elizabeth A. Jacobs, MD, MAPP, FACP, Co-Chair



PCORI Topic Brief Discussion Criteria

1. **Patient-Centeredness:** Is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
2. **Impact of the Condition on the Health of Individuals and Populations:** Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity or individual suffering?
3. **Assessment of Current Options:** Does the topic reflect an important evidence gap related to current options that is not being addressed by ongoing research?
4. **Likelihood of Implementation in Practice:** Would new information generated by research be likely to have an impact in practice? (e.g., do one or more major stakeholder groups endorse the question?)
5. **Durability of information:** Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?



Sleep Apnea Topic Brief Discussion

- What is the comparative effectiveness of medical and surgical treatment options for racial/ethnic minority adults with obstructive sleep apnea?
 - Primary Discussant:
 - Patrick Kitzman, PhD, MS
 - Secondary Discussant:
 - Christine Joseph, PhD, MPH



PCORI Topic Brief Discussion Criteria

1. **Patient-Centeredness:** Is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
2. **Impact of the Condition on the Health of Individuals and Populations:** Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity or individual suffering?
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4. **Likelihood of Implementation in Practice:** Would new information generated by research be likely to have an impact in practice? (e.g., do one or more major stakeholder groups endorse the question?)
5. **Durability of information:** Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?



Eye Drops vs Laser Trabeculoplasty Discussion

- What is the comparative effectiveness of eye drops versus laser trabeculoplasty to reduce excess morbidity from open-angle glaucoma in black and Hispanic individuals?
 - Primary Discussant:
 - Alan R. Morse, PhD, JD, MS
 - Secondary Discussant:
 - Tung Nguyen, MD



PCORI Topic Brief Discussion Criteria

1. **Patient-Centeredness:** Is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
2. **Impact of the Condition on the Health of Individuals and Populations:** Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity or individual suffering?
3. **Assessment of Current Options:** Does the topic reflect an important evidence gap related to current options that is not being addressed by ongoing research?
4. **Likelihood of Implementation in Practice:** Would new information generated by research be likely to have an impact in practice? (e.g., do one or more major stakeholder groups endorse the question?)
5. **Durability of information:** Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?



Topics Under Consideration: Readmissions and Autism

Romana Hasnain-Wynia, PhD, MS

Program Director, *Addressing Disparities*

Ayodola Anise, MHS

Program Officer, *Addressing Disparities*



Topics Under Consideration: Readmissions

- Readmissions was discussed with the panel during the February and June 2016 meetings.
- The panel identified and discussed the following comparative effectiveness question:
 - “Compare the effectiveness of approaches (e.g., telephone management post discharge, clinic visits, telephone management, supportive services) to prevent hospital readmission for patients at high risk for readmission including racial/ethnic minorities, patients with limited English proficiency, patients with low health literacy, underinsured, and others”
- The panel was very enthusiastic and gave strong endorsement to move forward with this topic



Topics Under Consideration: Readmissions (cont.)

- **24 projects** in PCORI's Science portfolio are related to readmissions or include readmissions as an outcome.
- The majority of studies are located in **IHS** and **CER Programs**; only **2** in **Addressing Disparities Program**.
 - *A Comprehensive Disease Management Program to Improve Quality of Life in Disparity Hispanic Patients Admitted with Exacerbation of Chronic Pulmonary Diseases*
 - Compares standard Pulmonary Rehabilitation (PR) and telehealth PR
 - *Improving Health Outcomes among Native Americans with Diabetes and Cardiovascular Disease*
 - Study is observational and evaluates how use of education, case management, and advanced practice pharmacy services influences patient outcomes



Topics Under Consideration: Readmissions (cont.)

- The topic Readmissions was presented to the Science Oversight Committee in July 2016
 - The Science Oversight Committee raised concerns about the topic being too broad.
 - It was recommended that a more concrete condition should be evaluated in relation to readmissions



Topics Under Consideration: Readmissions (cont.)

Discussion:

- Should readmissions related to specific conditions be evaluated?
- Should alternative methods other than comparative effectiveness research (e.g., Meta analysis, systematic review, literature review) be used to address this question?



Topics Under Consideration: Autism

- AD Advisory Panel input and feedback from the July 2016 meeting on autism spectrum disorders (ASD) was shared with PCORI Science leadership to determine next steps.
- PCORI staff have engaged multiple stakeholders (e.g., payers, National Business Group on Health) to discuss areas of potential need, impact, and interest in development of a large targeted funding announcement.
- “Treatment strategies for patients with ASD” is a priority topic for the Pragmatic Clinical Studies Funding Announcement
 - Perform large scale, multi-center, RCT or well designed observational study with long-term follow-up comparing the effectiveness of applied behavioral analysis (in children 2-5 years old) with accepted treatments for alleviating externalizing and internalizing behavior and improvement social skills, patient-child interactions, family well-being, and other patient-relevant outcomes (e.g., changes in core and associated symptoms). Studies should be sufficiently large to permit rigorous analysis of HTE related to provider, parent, family, child, intervention, and other characteristics.



Discussion

Evidence Synthesis to Inform CER

Evelyn Whitlock, MD, MPH

Chief Scientific Officer, *Patient-Centered Outcomes Research Institute (PCORI)*



CSO Vision



Vision

- “One Science”
 - Consistent approach and supportive response to applicants and awardees
 - Strategic thinking around portfolio
 - Excellence, collegiality, camaraderie across and beyond department
- 2016 Goals
 - Establish Evidence Synthesis Program
 - Enhance integration of scientific programs within department and across PCORI
 - Improve interface and relationships with the researcher community
 - Align mission of advisory panels to overall PCORI direction



PCORI RESEARCH FRAMEWORK

Producing the comparative clinical effectiveness research (CER) evidence to improve patient-centered outcomes and inform value considerations in healthcare decisions by patients, clinicians, payers, and policy makers.

PCORI RESEARCH FRAMEWORK

APPLICABLE EVIDENCE



INFORMED DECISION MAKING

WHAT CARE IS
BETTER FOR
INDIVIDUAL
PATIENTS?

HOW CAN
PATIENT-CENTERED
CARE BE BEST
DELIVERED?

COMPARATIVE
CLINICAL
EFFECTIVENESS
RESEARCH

IMPROVING
HEALTH
SYSTEMS

ADDRESSING
DISPARITIES

COMMUNICATION
RESEARCH

IMPROVING METHODS

EVIDENCE SYNTHESIS

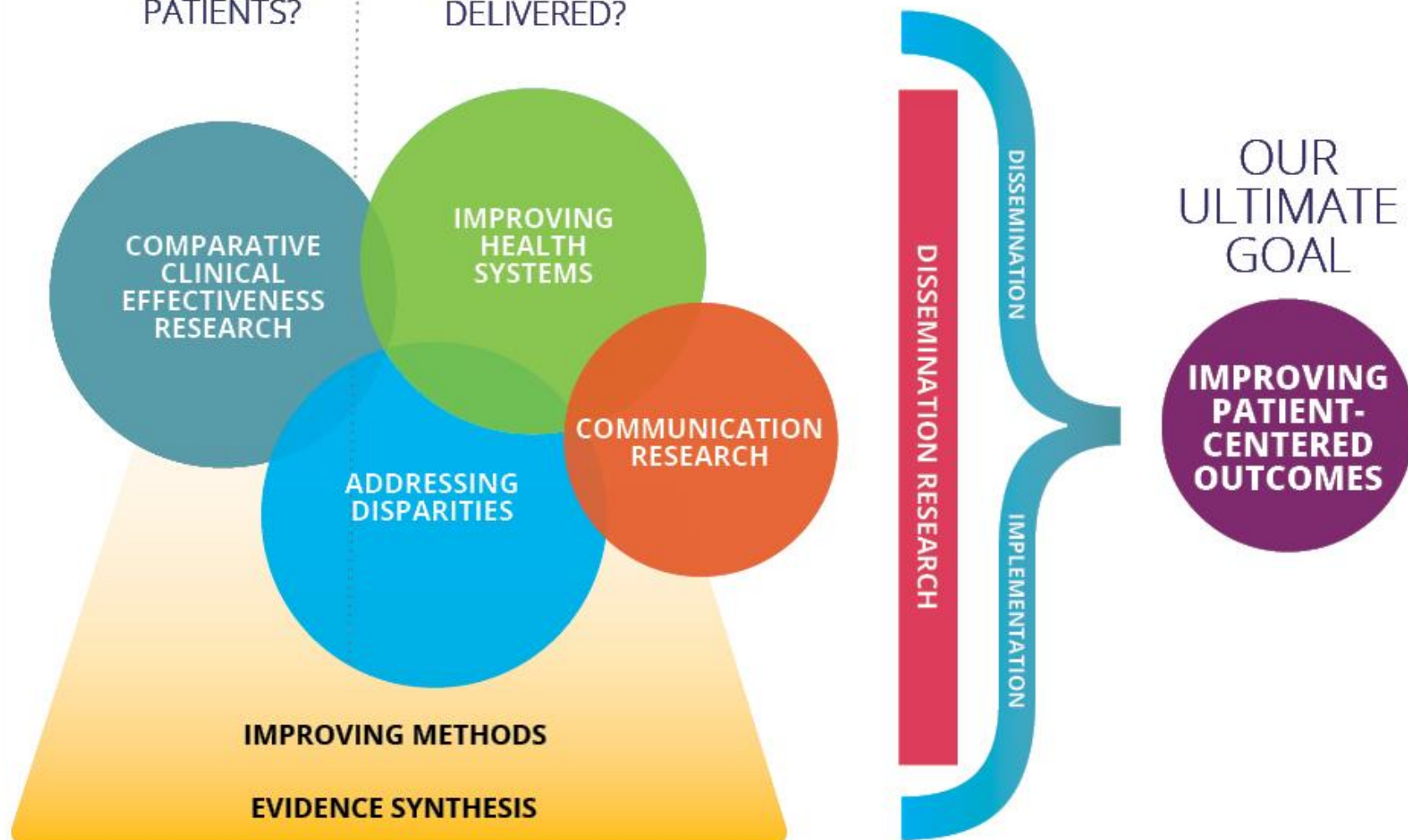
DISSEMINATION RESEARCH

DISSEMINATION

IMPLEMENTATION

OUR
ULTIMATE
GOAL

IMPROVING
PATIENT-
CENTERED
OUTCOMES



Research Synthesis Program

- Research synthesis is an umbrella term for a set of related activities at PCORI
 - More rapid deployment of actionable CER evidence in context
 - New research to address individual choices and treatment matching
 - Communication of current portfolio themes and learnings



Research Synthesis Program

- “Research synthesis” acknowledges various levels and methods:
 - Evidence Synthesis (e.g., systematic review)
 - Qualitative and/or quantitative methods
 - Variation in treatment effect/“personalized” medicine
 - Synthesis of PCORI’s research investments
(e.g., portfolio “cluster” analyses, portfolio mapping)
 - Identification and synthesis of a body of relevant research
(e.g., evidence maps)

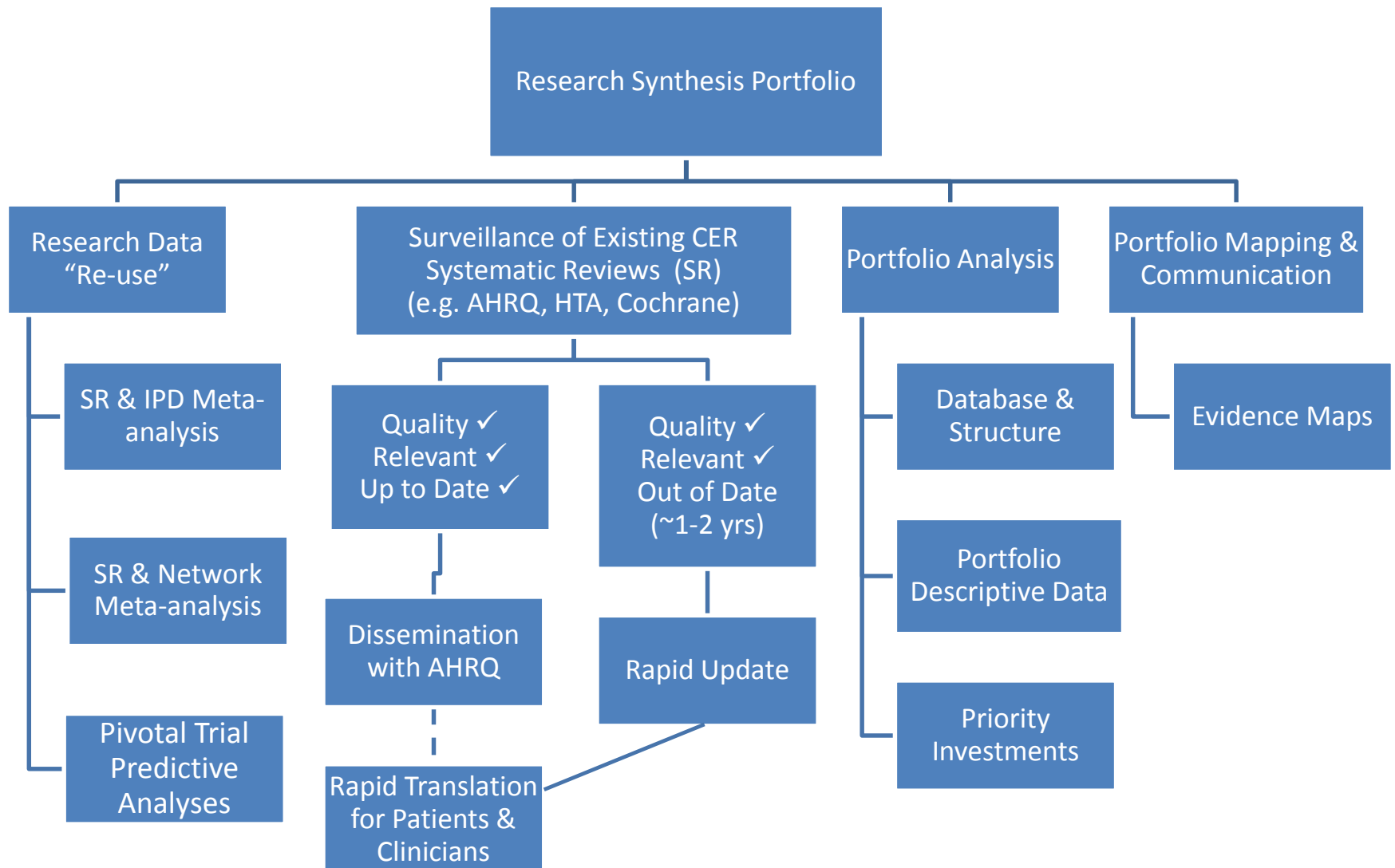


Research Synthesis—Immediate Plans


- For the present, the Research Synthesis portfolio will focus on **short-turnaround, rigorous, relevant** CER or heterogeneity of treatment effect products
 - Strategic, selective focus on generating new research products
 - Also, locating and qualifying existing CER products for immediate dissemination or updating



Research Synthesis Program Overview



Evidence Map – Example HIV

Confidence in the validity of strategy				
<div><div>High</div><div>Medium</div><div>Low</div><div>Prevalence</div></div>				
Interventions / Outcomes	Awareness, knowledge	Attitudes and Beliefs	Risk behaviour / skills	HIV transmission
 Behaviour change interventions	Peer Education	Prevention for heterosexual men	Behaviour change interventions for women	
	Prevention for heterosexual men	Peer interventions	Couples-focused behavioural interventions	Challenges in HIV prevention research
	Peer interventions	ICT for youth	Condom use for HIV positive women	Behaviour interventions for prevention
	Prevention in Latin America		Peer Education	
	ICT for youth		Prevention in heterosexual men	Prevention in occupational settings
			Behaviour interventions for prevention	School based interventions for youth
			Influence of social agents	
			Peer interventions	
			Prevention in Latin America	
			ICT for youth	
			Prevention in occupational settings	
			School based interventions for youth	
Condom promotion distribution	Prevention for youth in Africa			
Information, education and communication	Educating traditional healers	School-based sexual health in Africa	Educating traditional healers	Prevention for youth in Africa
	School-based sexual health in Africa	Peer-led sexual health education for youth	Prevention for youth in Africa	Prevention in African youth
	Peer-led adolescent sexual health education	Life skills education for youth	School-based sexual health interventions in Africa	Girls' education
	Life skills education for youth	Parent-child communication in Africa	Peer-led sexual health education for youth	Peer-based interventions for HIV positive women
			Life skills education for youth	
			Parent-child communication in Africa	
			Prevention in African youth	
			Girls' education	
			Peer-based interventions for HIV positive women	
	Mass communication	Mass communication programmes		



Different Types of Meta-analysis

- Individual patient-level data (IPD) meta-analysis obtains and synthesizes *individual-level data* from multiple related studies
- Advantages of IPD-MA (“gold standard”):
 - Can standardize variables and analyses across studies
 - Differential treatment effects can be robustly assessed for subgroups, particularly based on multiple factors
 - More accurate risk-of-bias assessments
 - May have more up-to-date follow-up information compared to the original publications
 - New analytic opportunities (e.g., time-to-event analyses)



IPD MA Opportunity for Progesterone and Preterm Birth

- Preterm birth is a critical disparities issue
- Progesterone and PTB prevention was identified as a high-priority topic by engagement with March of Dimes (MOD)
- A topic brief was discussed with the Advisory Panel for APDTO; the panel did not feel that a new trial is appropriate at this time, given pending FDA work
- MOD was interested in additional opportunities, given the importance of this topic, and current controversies in the existing literature and guidelines
- IPD MA was suggested in *Lancet* article February 2016
- We “proofed” the need by reviewing previous study and IPD-level MA and current controversies
- We initiated contact to join the planning group as a co-funder with MOD and NIHR and attended the international meeting



Preterm birth: the problem (and the opportunity)

- Definition: delivery before 37 weeks of pregnancy
- 11.4% of U.S. babies are born preterm
 - 13.3% of African American babies are born preterm
 - Worldwide, ranges from 5%-18%
- Most common cause of infant death:
50-75% attributable risk
- Annual US societal economic cost was ≥ \$26 billion
in 2005

*Source: March of Dimes Foundation Data
Book for Policy Makers: 2014*



Preterm birth: the problem (and the opportunity)

- Leading cause of long-term disability in children:

Disability	Gestational age at birth	Relative risk (95% CI)
Cerebral palsy	23 w to 27 w 6 d	79 (56-110)
	28 w to 30 w 6 d	46 (37-57)
Blindness, low vision, hearing loss, epilepsy	23 w to 27 w 6 d	20 (12-32)
	28 w to 30 w 6 d	9 (7-13)
Any disability severely affecting work capacity	23 w to 27 w 6 d	8 (6-10)
	28 w to 30 w 6 d	5 (4-6)



Preterm Birth: a multifactorial syndrome

- Risk factors include:
 - Prior history of preterm birth
 - Multiple pregnancy
(increasingly common with IVF)
 - Shortened cervix (usually measured during the fetal anatomic survey ultrasound [18-22 weeks])
 - Positive fetal fibronectin test
 - Very young or advanced maternal age
- Interventions include:
 - Cerclage (cervical stitch)
 - Pessary (intravaginal support)
 - Progesterone (oral, injection, vaginal)
 - Prenatal interventions
(e.g., pregnancy spacing)

Preterm birth has multiple causes and approaches to prevention: not every intervention is appropriate for every situation. The opportunity here is to better discriminate the exact circumstances under which progesterone is most effective.



Discussion

PCORI's National Priority for Research and Programs

Romana Hasnain-Wynia, PhD, MS

Program Director, *Addressing Disparities*



PCORI's National Priority for Research and Programs: Presentation Goals

- Present a high-level overview of PCORI's four other programs



PCORI's National Priorities for Research



**Assessment of Prevention,
Diagnosis, and Treatment Options**



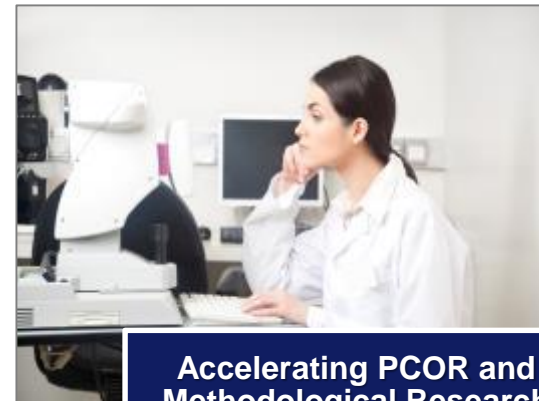
**Improving Healthcare
Systems**



**Communication &
Dissemination Research**



Addressing Disparities



**Accelerating PCOR and
Methodological Research**



PCORI's Authorizing Legislation

PCORI's authorizing legislation states that:

“(C) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations....”



Clinical Effectiveness Research Program

Mission Statement

Develop new evidence for comparing the effectiveness and safety of different clinical options to see which ones work best for different people with a particular health condition or concern.

Research Priority

Research that compares the outcomes of two or more healthcare options already shown to be efficacious



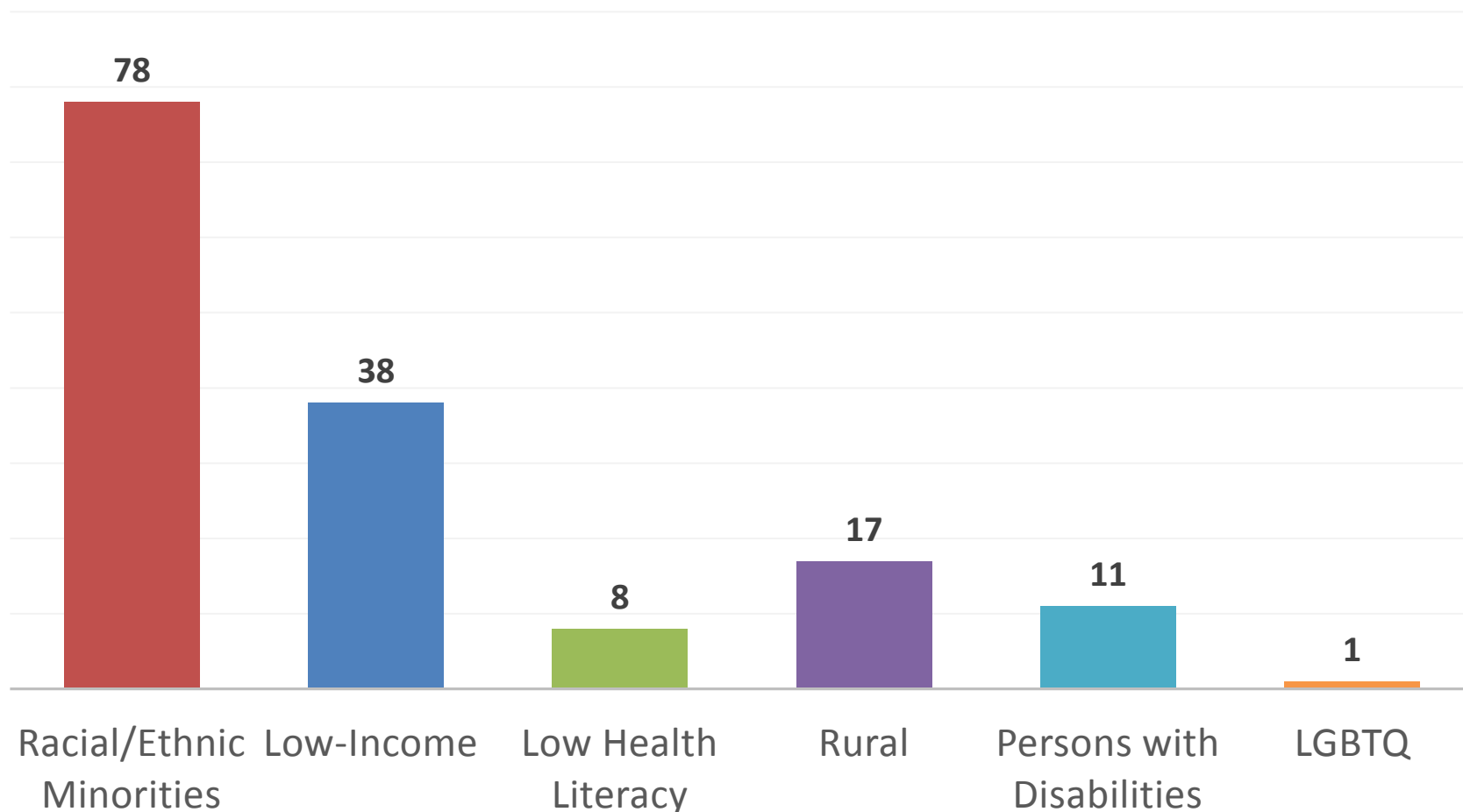
Clinical Effectiveness Research Portfolio – Health Conditions

Condition	Number
Cancer	26
Rare Diseases	18
Mental/ Behavioral Health	15
Neurological Disorders	16
Cardiovascular Health	15
Muscular and Skeletal Disorders	9
Other	40
Grand Total	139



Addressing Disparities Populations of Interest within the Clinical Effectiveness Research Portfolio

*not mutually exclusive



Improving Healthcare Systems Program

Mission Statement

Compare healthcare system interventions that are intended to optimize the quality, outcomes, and/or efficiency of patient care and that have the greatest potential for sustained impact/replication

Research Priority

To support studies of the comparative effectiveness of alternative features of healthcare systems that will provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders, regarding which features of systems lead to better patient-centered outcomes



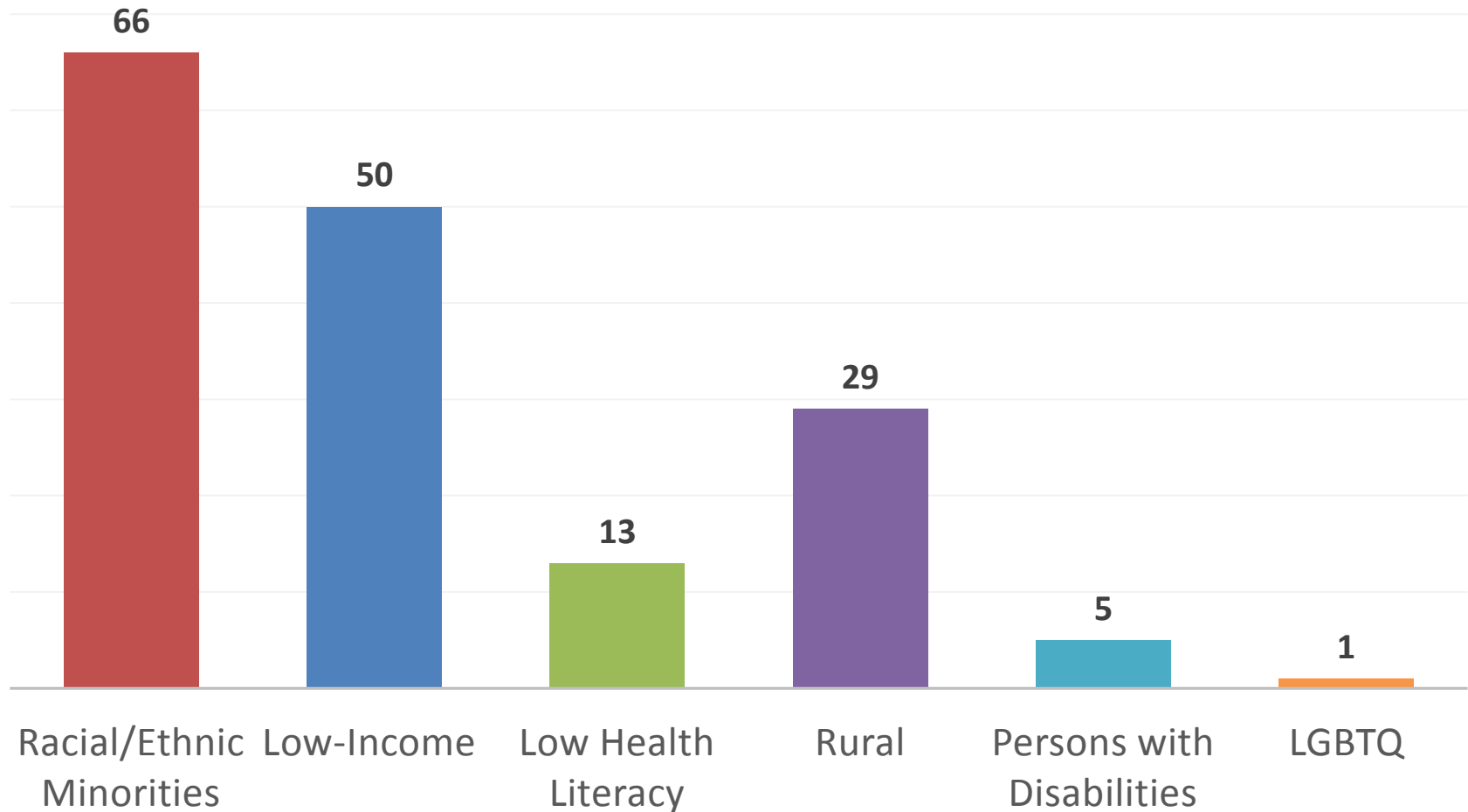
Improving Healthcare Systems Portfolio - Health Conditions

Condition	Number
Mental/ Behavioral Health	19
Cancer	10
Nutritional and Metabolic Disorders	10
Non-Disease Specific	10
Neurological Disorders	6
Multiple/Co-Morbid	5
Cardiovascular Health	5
Trauma/Injury	5
Other	16
Grand Total	86



Addressing Disparities Populations of Interest within the Improving Healthcare Systems Portfolio

*not mutually exclusive



Communication and Dissemination Research Program

Mission Statement

Compare approaches to provide CER information, empower people to ask for and use the information, and support shared decision making between patients and their providers

Research Priority

Communication and dissemination strategies to promote the use of health and health care CER evidence by patients, caregivers, and clinicians



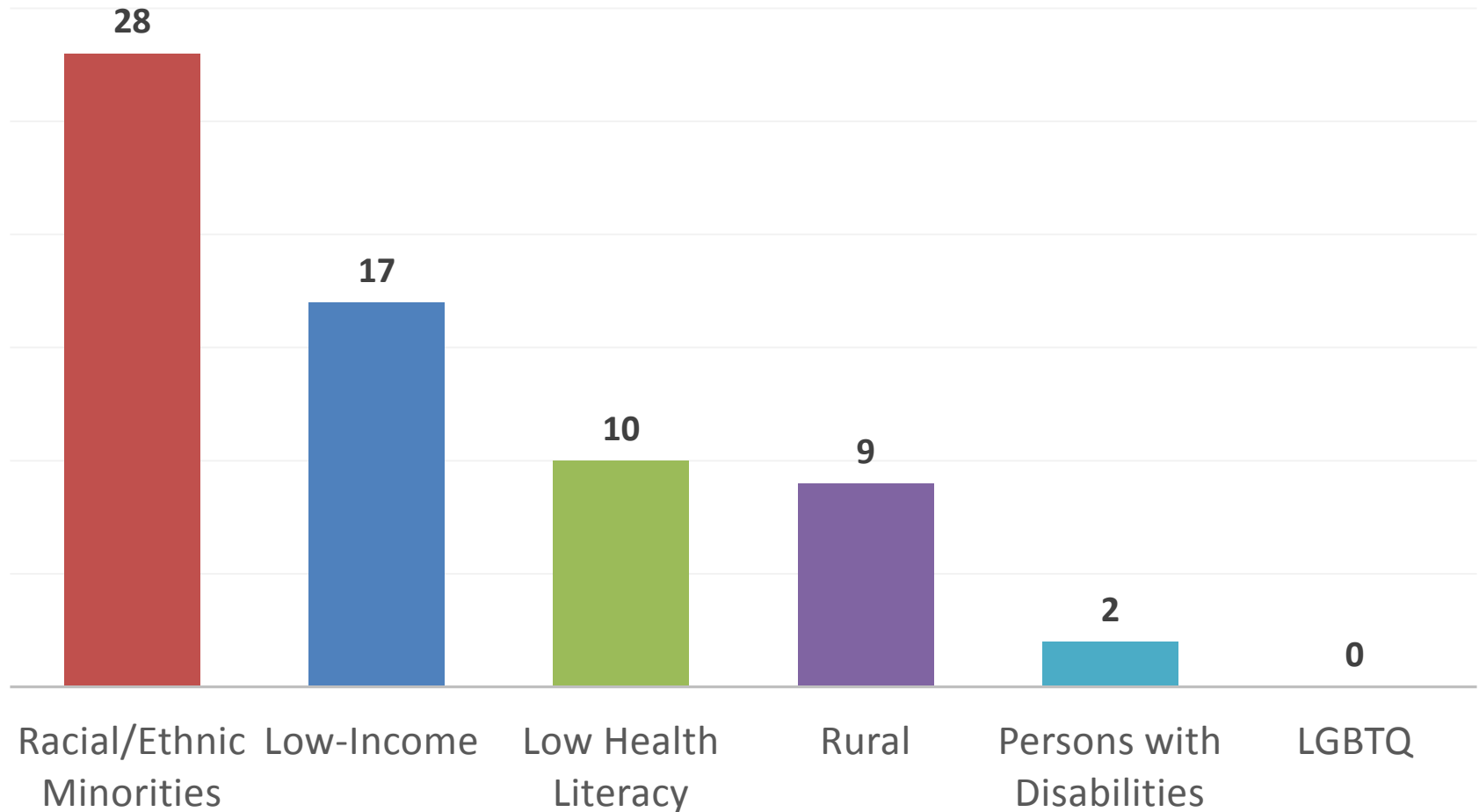
Communication and Dissemination Research Portfolio - Health Conditions

Condition	Number
Non-disease Specific	10
Cancer	8
Mental/ Behavior Health	6
Reproductive and Perinatal Health	6
Multiple/ Co-Morbid Chronic Conditions	5
Cardiovascular Health	3
Respiratory Disease	3
Neurological Disorders	2
Rare Disease	1
Grand Total	44



Addressing Disparities Target Populations of Interest within Communication and Dissemination Research Program Portfolio

*not mutually exclusive



Clinical Effectiveness Research Methods

Mission Statement

Improve methods regarding the design and conduct of clinical studies, thereby improving the nation's capacity to conduct patient-centered CER

Research Priority

High-priority methodological research topics in PCOR and comparative clinical effectiveness research



Clinical Effectiveness Research Methods Portfolio – Research Methods Types

Research Method Types	Number
Non-disease Specific	160
All Conditions/Diseases	3
Nutritional and Metabolic Disorders	2
Cardiovascular Health	1
Grand Total	166



Discussion

Wrap Up and Next Steps



Adjourn

Thank you for your participation!